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In the

# Supreme Court of the United States

VALLEY DRUG COMPANY,
LOUISIANA WHOLESALE DRUG COMPANY, INC.,
*Petitioners,*

-against-

GENEVA PHARMACEUTICALS, INC.,
ABBOTT LABORATORIES,
*Respondents.*

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## ON A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

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## QUESTION PRESENTED

Whether an agreement whereby a patent holder pays its competitors not to compete is a *per se* violation of Section 1 of the Sherman Act.

## PARTIES TO THE PROCEEDING

In addition to the parties named in the caption, the following parties appeared below:

AARP (Amicus)
Albertson's Inc.
American Antitrust Institute
CVS Meridian, Inc.
Eckerd Corporation
Florida Attorney General (Amicus)
Hy-Vee, Inc.
Kroger Co.
National Association of Chain Drug Stores (Amicus)
Pennsylvania Attorney General (Amicus)
Right Aid Corporation
Walgreens Co., Inc.
Washington Legal Foundation (Amicus)

## CORPORATE DISCLOSURE STATEMENT

Petitioner Louisiana Wholesale Drug Company, Inc. does not have a parent corporation and no publicly traded company owns 10% or more of Louisiana Wholesale Drug Company, Inc.'s stock. Petitioner Valley Drug Company is a wholly-owned subsidiary of DrugMax, Inc., a publicly-held company.

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## OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-39a) is reported at 344 F.3d 1294 (11th Cir. 2003). The district court's opinion (Pet. App. 42a-67a) is reported at 164 F.Supp.2d 1349 (S.D. Fla. 2000).

## STATEMENT OF JURISDICTION

The court of appeals judgment was entered on September 15, 2003. Pet. App. 1a. A timely petition for rehearing en banc was denied on November 18, 2003. Pet. App. 40a. The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

## STATUTORY PROVISIONS INVOLVED

Portions of Section 1 of the Sherman Antitrust Act, 15 U.S.C. §1 and the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (Hatch-Waxman Act) are reproduced at Pet. App. 68a-74a.

## STATEMENT OF THE CASE

This case involves a split between the Sixth and Eleventh Circuits in indistinguishable cases addressing the issue of whether it is a *per se* violation of Section 1 of the Sherman Act for a patent holder to pay its competitors not to compete during the pendency of a patent challenge. *Compare Valley Drug Co. v. Geneva Pharms. Inc.*, 344 F.3d 1294 (11th Cir.), *reh'g denied* (11th Cir. 2003)(Pet. App. 1a) *with In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir.), *reh'g denied* (6th Cir. 2003)(Pet. App. 75a).

Petitioners are direct purchasers of Hytrin from Abbott Laboratories ("Abbott"). Hytrin is brand-name drug with the active ingredient dihydrate terazosin hydrochloride used to treat hypertension and enlarged prostate. Petitioners brought this antitrust action after Abbott entered into agreements with two of its generic competitors, Geneva Pharmaceuticals, Inc. ("Geneva") and Zenith Goldline Pharmaceuticals, Inc. (now known as IVAX Pharmaceuticals, Inc.) ("Zenith").[1] Pet. App. 111a-141a. Pursuant to these agreements, Abbott paid Geneva and Zenith tens of millions of dollars not to market any generic versions of Abbott's highly profitable brand-name drug, Hytrin, in the United States, on the assumption that Geneva was willing to launch its product and assume the risk that it would owe substantial damages if Abbott's patent was later upheld. Prior to these agreements, Geneva had received final Food and Drug Administration ("FDA") approval to market its generic terazosin and Abbott had not sought, much less obtained an injunction to prevent Geneva from marketing its product. Therefore, assuming that Geneva was prepared to exercise its own business judgment and launch its product during the pendency of the patent controversy, there was no legal impediment that precluded Geneva from marketing its product.

The Eleventh Circuit, on the record before it, refused to find that the agreements between these competitors were *per se* violations of § 1 of the Sherman Act because it found that upon the issuance of a patent, a patent holder has a "right to exclude" competing products and, despite the payments here by the patent holder to the alleged infringer, the exclusionary effects of the agreements were possibly no greater than the

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[1] Petitioners settled their claims against Zenith. The District Court approved this settlement with Zenith on June 13, 2002.

exclusionary effect of the patent alone. Pet. App. 20a-24a. The Eleventh Circuit premise was flawed – the United States Patent and Trademark Office's issuance of a patent does not give a patent holder an absolute "right to exclude". Under patent laws, there was only *some probability* that Abbott would have been able to exclude generic products before an adjudication on the merits by (a) creating a fear in Geneva of damages in patent litigation[2] or (b) obtaining a preliminary injunction from the court, which would have required Abbott to demonstrate, *inter alia*, that it was likely to succeed on the merits and that the public would not be harmed by the injunction. *See, e.g., Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1219 (Fed. Cir. 1996); *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991). Abbott's payment to Geneva bolstered its *possible* right *to exclude* competitors (by meeting the strict requirements for a preliminary injunction or threatening to obtain damages in the infringement suit) into an *absolute, guaranteed* power to exclude. This Court has long held that if the challenged restraint bolsters the exclusionary power arising from the patent rights, then the ordinary rules of antitrust law govern and the court's decision to apply the *per se* rule or the rule of reason is determined, as in all other antitrust cases, by the nature of the restraint. *See, e.g., United States v. Line Material Co.*, 333 U.S. 287, 300 (1948); *Sola Elec. Co. v. Jeff Elec. Co.*, 317 U.S. 173 (1942); *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942).

The Sixth Circuit, in contrast, in an indistinguishable case, found that such an agreement "was, at its core, a horizontal agreement to eliminate competition in the market for

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[2] *See, e.g., In re Cardizem CD Antitrust Litigation*, 105 F.Supp.2d 682, 705 (2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003)(noting that a generic manufacturer may enter the market upon receipt of FDA approval).

Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade." Pet. App. 95a. The Sixth Circuit recognized that Hoeschst Marion Roussel's ("HMR") right as a patent holder to exclude competition was not absolute. The Sixth Circuit found that "the Agreement *guaranteed* to HMR that its only potential competitor at that time, Andrx, would, for the price of $10 million per quarter, refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval...." Pet. App. 94a. The Sixth Circuit held "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." Pet. App. 95a.

The issue splitting the courts is one of vital public importance. Consumers are poised to benefit from the imminent onset of generic competition for brand-name drugs with annual sales of more than $20 billion. 66 Fed. Reg. 12512, 12513 (2001). The Eleventh Circuit's opinion could legitimize the use of similar non-competition agreements to halt this imminent competition and the consumer benefit that it promises.

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This Circuit split arose in the context of legislation enacted by Congress in 1984, the Hatch-Waxman Act, formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355). The Hatch-Waxman Act was intended to increase the availability of lower-cost generic drugs. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, 27 (July 1998) ("One

of [its] primary goals was to increase the availability of lower-cost generic drugs.") On average, the price of generic drugs is less than half that of their brand-name counterparts. *Id.* at 31. To expedite the approval process and hence such drugs' availability, the Hatch-Waxman Act allows a manufacturer seeking to market a generic bioequivalent of an FDA-approved drug to file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). Allowed to rely upon the safety and effectiveness data submitted to the FDA by the manufacturer of the pioneer drug, *id.*, the generic manufacturer can substantially shorten the time required to gain approval of the generic bioequivalent. Prior to the Hatch-Waxman Act, a manufacturer seeking to market a generic version of an FDA-approved brand-name drug had to file a plenary New Drug Application ("NDA"), complete with new studies demonstrating the drug's safety and effectiveness. *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998).

The generic manufacturer must include in its ANDA a certification that: (I) no patent for the drug for which the ANDA is being submitted has been filed ("Paragraph I Certification"); (II) the patent for the drug has expired ("Paragraph II Certification"); (III) the applicant is seeking approval to market its drug after the expiration of the innovator's patent ("Paragraph III Certification"); or (IV) the patent for the drug is invalid or will not be infringed by the proposed generic version of the drug ("Paragraph IV Certification"). 21 U.S.C. § 355(j)(2)(A)(vii). These certifications determine the date on which approval of the ANDA can become effective and, therefore, the date on which commercial sale of the generic product may begin. *Eli Lily & Co. v. Medtronic*, 496 U.S. 661, 677 (1990).

If the ANDA applicant makes a Paragraph IV

Certification, the effective date of approval depends upon the outcome of further events triggered by the Hatch-Waxman Act. The ANDA applicant who includes a Paragraph IV Certification must give notice to the patent holder stating that an application has been filed seeking approval to market a generic product prior to the expiration of the patent and detailing the factual and legal basis for the applicant's belief that the patent is invalid or will not be infringed. 21 U.S.C. §§ 355(b)(3)(B) and (j)(2)(B)(ii). If the patent holder sues for patent infringement within forty-five days of receiving notice, then approval may not be made effective until the court rules that the patent is invalid or not infringed, or until the expiration of thirty months, whichever is sooner. 21 U.S.C. §§ 355(c)(3)(C) and (j)(5)(B)(iii).

Significantly, the Hatch-Waxman Act grants the first applicant to file an ANDA containing a Paragraph IV Certification a 180 day exclusivity period in which to market its generic drug without competition from other ANDA applicants. No other applications for approval of a bioequivalent drug may be granted until this 180-day period has expired. Congress enacted the 180-day provision specifically in order to create a strong incentive for generic drug manufacturers to challenge the validity of patents on brand-name pharmaceuticals. *Pharmachemie B.V. v. Barr Labs., Inc.*, 276 F.3d 627, 629 (D.C. Cir. 2002). However, until very recent legislation,[3] the

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[3] The Medicare Prescription Drug Improvement and Modernization Act of 2003 was signed into law on December 8, 2003, PL. No.108-173. This legislation strips the first ANDA filer of its 180-day exclusivity period if it fails to exercise its right to come to market in a timely fashion. PL. No. 108-173, § 1102. Failure to come to market within 75 days of a qualifying court judgment or settlement will cause the total forfeiture of the generic company's 180-day exclusivity period.

180-day exclusivity could begin only: (1) upon the commercial marketing of the drug by the first applicant; or (2) when a court issues an unappealable ruling finding the patent to be invalid or not infringed, whichever is earlier. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day exclusivity period is a valuable commodity that can be sold or waived for substantial consideration. This might happen if, for example, the first-filer was not prepared to launch but a subsequent ANDA filer was. *See, e.g., Mylan v. Shalala*, 81 F. Supp. 2d 30, 42 (D.D.C. 2000).

As a result, if the patent holder pays the first applicant to not market its drug and if no final court ruling issues within the thirty months, the patent holder and the first applicant can effectively delay the onset of generic competition entirely. *Mova*, 140 F.3d at 1067. This is an abuse of the Hatch-Waxman Act's purpose: "to bring generic drugs on the market as rapidly as possible." *Id.* at 1068. *See also* 64 Fed. Reg. 42,874-75 (Aug. 6, 1997) (agreement between patent holder and generic drug company that contributes to delayed generic competition by forestalling the beginning or triggering of the 180-day exclusivity period, "thwart[s] a major Congressional goal underlying the passage of the Hatch-Waxman Amendments.").

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On April 29, 1996, Geneva filed separate ANDAs seeking FDA approval to manufacture and market generic capsule and tablet bioequivalent versions of Hytrin, Abbott's brand-name drug with the active ingredient dihydrate terazosin hydrochloride used to treat hypertension and enlarged prostate. Geneva filed "Paragraph IV Certifications," certifying that any patents on the Hytrin pioneer drug, including U.S. patent No. 5,504,207 ("the '207 patent") were invalid or would not be

infringed by the generic drug. Geneva was the first company to file Paragraph IV Certifications to Abbott's terazosin hydrochloride '207 patent. As required by the statute, Geneva notified Abbott, the patent owner, of the ANDA filings and Paragraph IV Certification. 21 U.S.C. § 355(j)(2)(B)(1). In response, within forty-five days of receiving notice of Geneva's Paragraph IV certification, Abbott commenced a patent infringement action against Geneva, asserting that the Geneva's tablet terazosin hydrochloride product infringed Abbott's '207 patent, thus triggering a statutory thirty-month waiting period before the ANDA could receive the FDA's final approval and Geneva could begin selling its generic drug. 21 U.S.C. § 355(j)(5)(B)(iii). However, Abbott did not sue Geneva on its generic capsule version of Hytrin within forty-five days following Geneva's notice. As a result, the stay of final approval did not apply to the generic capsule version.

Zenith, another generic competitor of Abbott's, also sought FDA approval to produce generic versions of Hytrin. However, in an attempt to avoid the thirty month stay of approval and Geneva's 180-day exclusivity period as the earlier filed ANDA, Zenith brought suit seeking to force Abbott to delist its '207 patent, relieving Zenith of the obligation to make a Paragraph IV certification and seeking a declaration that its product did not infringe Abbott's patents.[4] Zenith's suit alleged that Abbott listed the '207 patent knowing that it did not claim

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[4] Under the Hatch-Waxman Act, a pioneer drug manufacturer that holds an approved NDA is required to notify the FDA of all patents which claim the drug or which claim a method of using such a drug and with respect to which a claim of patent infringement could reasonably be asserted. 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists such patents in its Approved Drug Products With Therapeutic Equivalence Evaluations (otherwise known as the "Orange Book").

Hytrin or a method of using Hytrin. Abbott counterclaimed for infringement. Zenith's attempt to obtain a preliminary injunction against the listing of the patents was unsuccessful. *See Zenith Labs. v. Abbott Labs.* No. 96-1661, 1997 U.S. Dist. LEXIS 23954 (D.N.J. Oct. 1, 1997). Zenith appealed the denial to the Federal Circuit.

Geneva received final FDA approval to market and sell its generic capsule version of Hytrin on March 30, 1998 and its generic tablet version of Hytrin on December 31, 1998, after the thirty-month waiting period (which applied only to the tablet) had expired.

On April 1, 1998, two days after Geneva received final FDA approval of its generic, capsule version of Hytrin, Abbott and Geneva entered into the agreement at issue here (the "Agreement"). Pet. App. 111a. Pursuant to the Agreement, Geneva agreed that in exchange for Abbott's promise to pay it $4.5 million per month, Geneva would "not sell, offer for sale, donate or otherwise distribute in the United States any Terazosin Hydrochloride Product...." Pet. App. 118a. The Agreement did not settle the patent litigation between Abbott and Geneva. Rather, under the Agreement, Geneva was to stay off the market until: (a) another patent owned by Abbott but not the subject of the pending litigation between Abbott and Geneva (U.S. Patent No. 4,251,532) expired (in February 17, 2000);[5] (b) another generic version of Hytrin had entered the market; or (c) a final, unappealable judgment had been rendered in the patent infringement suit brought by Abbott against Geneva's generic, tablet version of Hytrin, whichever occurred first. The latter condition required a final judgment from which

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[5] In 1993 Abbott sued Geneva for infringing the '532 patent, but voluntarily dismissed that action less than a year after it was filed.

no further appeal could be taken, including resolution of any petition for certiorari to this Court. Pet. App. 113a-114a.

In addition, Geneva agreed to (a) join and support any motion filed by Abbott seeking an extension of the thirty-month Hatch-Waxman waiting period and (b) use its best efforts to oppose attempts by any other ANDA applicant that was a party to litigation involving terazosin hydrochloride patents to obtain approval of an ANDA for a terazosin hydrochloride patent. Geneva agreed not to transfer or sell its rights under its ANDAs, including its right to the 180-day exclusivity period. Pet. App. 118a-119a. By its express terms, this contractually mandated delay in marketing the generic drug applied even if the drug infringed no patent held by Abbott.[6] Pet. App. 118a. The Agreement thus created a "bottleneck" that prevented not only Geneva, but also any other generic manufacture of Hytrin, from coming onto the market.

Absent the Agreement, Geneva could have chosen to enter the market with its generic product at any time after it received final FDA approval on March 30, 1998. Abbott could have foreclosed such competition only by obtaining a preliminary injunction from the patent court – which would have required Abbott to establish, *inter alia*, that it was likely to succeed on the merits of the patent suit and that the public would not be harmed by the injunction. *See, e.g.*, *Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1219 (Fed. Cir. 1996); *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991). Such a showing was extraordinarily unlikely. Indeed, on September 1, 1998, a few months after the

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[6] Abbott entered into a similar agreement with Zenith in which Zenith agreed to refrain from selling its generic version of Hytrin in return for quarterly payments of $6 million.

challenged agreement was executed, the district court hearing the patent case held the '207 patent invalid because the crystalline form of terazosin hydrochloride claimed in the patent was on sale in the United States more than one year before Abbott applied for the patent. *Abbott Labs. v. Geneva Pharms., Inc.*, Nos. 96-C-3331, 96-C-5868, & 97-C-7587, 1998 WL 566884 (N.D.Ill. Sept. 1, 1998). The order was affirmed by the Federal Circuit on July 1, 1999. *Abbott Lab. v. Geneva Pharm., Inc.*, 182 F.3d 1315 (Fed. Cir. 1999).

However, (a) even though Geneva received final FDA approval; (b) even after the automatic thirty month Hatch-Waxman stay had expired; (c) even though Abbott did not even attempt to make the showing of reasonable success on the merits to obtain a preliminary injunction; and (d) even after a district court and the Federal Circuit declared the '207 patent invalid, Geneva still could not enter the market because the Agreement prohibited entry until after the exhaustion of all appeals through the Supreme Court.[7]

Geneva continued to comply fully with the Agreement until August 13, 1999, at which time Abbott and Geneva terminated their agreement in the face of an FTC investigation. The FTC action resulted in a consent settlement. *See Matter of Abbott Labs.*, No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000).

Petitioners assert that but for the Agreement and the payment by Abbott to its two generic competitors, Geneva would have entered the generic Hytrin market promptly after receiving FDA approval for its generic capsule version of

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[7] Abbott's petition for certiorari was denied on January 10, 2000. 528 U.S. 1078, 120 S.Ct. 796, 145 L.Ed.2d 671 (2000).

Hytrin in March 1998, and it would have done so at a price substantially lower than that of the brand-name Hytrin sold by Abbott. The suit alleges that the Agreement unlawfully protected Abbott from competition not only from Geneva, but also from other potential generic competitors because of the 180-day exclusivity "bottleneck."

On December 13, 2000, the United States District Court for the Southern District of Florida granted plaintiffs' motion for partial summary judgment, ruling that the Agreement constituted an illegal market allocation agreement and was *per se* illegal. Specifically, the District Court, following long established Supreme Court precedent, found:

> Viewed together and in their factual context, these provisions illustrate that Geneva and Zenith forswore competing with Abbott in the United States market for terazosin hydrochloride drugs and promised to take steps to forestall others from entering that market for the life of their respective agreements in exchange for millions of dollars in monthly or quarterly payments.

Pet. App. 55a.

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> Abbott's agreements with Geneva and Zenith to forestall competition in the United States for sales of terazosin hydrochloride drugs confront the Court with "[o]ne of the classic examples of a *per se* violation" - "an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition." (*citing United States v.*

*Topco Associates Inc.*, 405 U.S. 596, 608 (1972)).

Pet. App. 56a.

Permission to take an interlocutory appeal from the order under 28 U.S.C. § 1292(b) was granted by the Eleventh Circuit. The Eleventh Circuit reversed the District Court's *per se* order, concluding that multi-million dollar payments to a competitor were possibly within the scope of Abbott's patent rights. Pet. App. 20a-24a. For the reasons discussed below, the petition should be granted because there is a split in the circuits on this important issue.

## REASONS FOR GRANTING THE PETITION

### I. This Court Should Grant the Petition to Resolve the Conflict Between the Circuits

There is a split in the circuits regarding the issue whether an agreement whereby a patent holder pays its competitors not to compete is a *per se* violation of Section 1 of the Sherman Act. The Eleventh Circuit and the Sixth Circuit reached opposite conclusions based on indistinguishable facts. Compare *Valley Drug Co. v. Geneva Pharms. Inc.*, 344 F.3d 1294 (11th Cir.), *reh'g denied* (11th Cir. 2003) (Pet. App. 1a) with *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir.), *reh'g denied* (6th Cir. 2003)(Pet. App. 75a).

The Eleventh Circuit refused to condemn such agreements as *per se* violations because it determined that upon the issuance of a patent, a patent holder has a "right to exclude" competing products and the exclusionary effects of the agreements therefore were possibly no greater than the exclusionary effect of the patent. Pet. App. 20a-24a. The Court

found that "[i]f this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order. This is not such a case, however, because one of the parties owned a patent." Pet. App. 20a. The Court held that because the generic companies' agreements to remain out of the market "appear[] to be no greater than the potential exclusionary effect of the '207 patent" they fall within "the heart of the patent right and cannot trigger the *per se* label." Pet. App. 22a.

The Eleventh Circuit's holding fails to follow the antitrust analysis set out by the Supreme Court long ago for cases involving patents. Under the traditional analysis the court must first examine the applicable patent law in order to determine the precise nature and scope of the exclusionary right granted by Congress. If the challenged restraint bolsters the exclusionary power arising from the patent rights, then the ordinary rules of antitrust law govern and the court's decision to apply the *per se* rule or the rule of reason is determined, as in all other antitrust cases, by the nature of the restraint. *See, e.g.*, *United States v. Line Material Co.*, 333 U.S. 287, 300 (1948); *Sola Elec. Co. v. Jeff. Elec. Co.*, 317 U.S. 173 (1942); *United States v. Masonite Corp.*, 316 U.S. 265, 277.

The Eleventh Circuit, rather than perform the crucial first step of carefully delineating the nature and scope of Abbott's patent rights, merely decreed that "Abbott had a lawful right to exclude competitors" and thus "it is not obvious that the competition was limited more than that lawful degree by paying potential competitors for their exit." Pet. App. 30a. By so doing, the Eleventh Circuit gave Abbott the *absolute* right to exclude competitors pending a judicial resolution of validity – a right that Congress has never provided to patent holders.

The Eleventh Circuit should have, but did not take into account, the following factors regarding Abbott's patent rights:

- A patent holder has no absolute right to exclude competing products. It has only a right *to try to exclude* competing products. The patent gave Abbott the ability to threaten to collect damages against Geneva for pretrial sales if Geneva decided to enter the market and the patent court subsequently found these sales to have been infringing. However, Congress did not provide, as it might have, that a patent issued by the Patent and Trademark Office is *conclusively* presumed to be valid. Instead, Congress provided that a patent enjoys a rebuttal presumption of validity and placed the burden on the patent holder to prove infringement. Indeed, in the forty Hatch-Waxman cases that have been litigated to final judgment, the generic manufacturer has been found not to have infringed a patent in twenty-nine of them. FTC, *Generic Drug Entry Prior to Patent Expiration,* at 19-20, (July 2002) (available at http://www.ftc.gov/os/2002/07/ genericdrugstudy.pdf).[8]

- A patent holder also has a conditional right to invoke the power of the court to exclude allegedly infringing products during the pendency of an infringement action if it can satisfy the strict requirements for entry of a preliminary injunction, including a showing that his

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[8] Taking the Eleventh Circuit's reasoning to its logical conclusion, if any of these successful generic litigants had launched their products at risk, the patent holder would be able to recover damages for the period in which the generic company entered the market up to the point that the patent was declared invalid or not infringed.

patent is likely to be found valid and that the public will not be harmed. Absent such a showing, the alleged infringer has a "right to compete." *Ill. Tool Works, Inc., v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990) (denying preliminary injunction and permitting market entry before resolution of the patent case).

- A patent holder has no right to exclude competition by resorting self help, even if it believes its patent is being infringed. The Supreme Court has rejected attempts to justify cartels on the ground that they were necessary to suppress "illegal" competition. *See, e.g., FTC v. Ind. Fed. of Dentists*, 476 U.S. 447, 461 (1986)("That a particular practice may be unlawful is not, in itself, a sufficient justification for collusion among competitors to prevent it"); *Fashion Orig. Guild, Inc. v. FTC*, 312 U.S. 457, 468 (1941)(prevention of illegal competition is no defense to Section 1 claim).

- There is explicit Congressional direction regarding generic entry during the pendency of patent litigation. The '207 patent allowed Abbott to exclude generic competition by filing an infringement suit and triggering the Hatch-Waxman Act's automatic thirty-month stay.[9] Abbott failed, however, to bring a timely suit regarding

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[9] In the Hatch-Waxman Act, Congress granted to holders of such patents thirty months of guaranteed exclusion pending resolution of a lawsuit initiated by the patent holder. 21 U.S.C. § 355(j)(5)(B)(iii). The automatic exclusion – which in original versions of the legislation was for only eighteen months – was part of the complex balancing by Congress between the rights of patent holders and those of consumers and generic manufacturers. *See* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 398-407 (1999) (reviewing legislative history).

Geneva's generic capsule. Hence, Abbott was not entitled to exclude Geneva (prior to a determination on the merits) other than by obtaining a preliminary injunction.

- Congress, not the courts, balances the competing interests of patent holders and consumers by specifying the patent rules; for example, the patent term shall be twenty years, not twenty-five; a patent shall have only a rebuttable, not a conclusive, presumption of validity; and, in the pharmaceutical area, patent holders meeting certain conditions are entitled to automatic exclusion for thirty months, not thirty-eight months, and only for up to thirty months, not longer, regardless of whether the patent litigation is pending. With Congress having balanced the relevant interests by specifying the applicable patent rules, the courts are without authority to undermine that balance by altering the antitrust laws to permit a patent holder to pay the challenger to recognize the patent for twenty-five years; to concede the validity of the patent; to stay out of the market beyond thirty months; or where no thirty month stay applies, to stay out of the market during the pendency of the patent litigation. As the Supreme Court held in *Line Material* and *Masonite*, courts must take the existing patent regime as a given and then apply the ordinary antitrust rules. *See Line Material*, 333 U.S. at 312 (the Sherman Act imposes limitations on the exploitation of patent rights); *Masonite*, cited *infra* (same). *See also Hartford-Empire Co. v. United States*, 323 U.S. 386, 433 (1945)("Congress [has] the power to fix...the life of a patent. No court can disregard any statutory provisions in respect to these matters on the ground that

> in its judgment they were unwise or prejudicial to the interests of the public." *quoting United States v. American Bell Telephone Co.*, 167 U.S. 224, 247 (1897)); *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1550 (Fed. Cir. 1994)(although Congress may provide for patent term extensions in appropriate circumstances, in the absence of such action a court cannot legislate in its place).

Because the Eleventh Circuit's conclusion failed to carefully identify the nature and scope of Abbott's patent rights to exclude competitors during the pendency of litigation and outside the Hatch-Waxman thirty-month stay, it failed to recognize that Abbott's "lawful right to exclude" was plainly conditional, not absolute. Under the patent rules as specified by Congress, there was only some (extraordinarily low) probability that Abbott would be able to exclude Geneva's generic products by obtaining a preliminary injunction from the court. The very fact that Abbott paid millions of dollars to an alleged infringer demonstrates that Abbott's '207 patent, standing alone, would not have been sufficient to keep Geneva from coming to market. Moreover, the non-absolute nature of Abbott's patent rights are underscored by the fact that its '207 patent was declared invalid in September 1998.

In enacting the patent laws and the Hatch-Waxman Act, Congress struck a balance between the rights of pharmaceutical patent holders to try to protect their patents and the rights of generic challengers to enter the market, if they are confident enough in their challenges, during the pendency of the patent suit. Abbott's payment bolstered its right from a *limited, conditional* right to exclude competitors to an *absolute* right. It allowed Abbott, without having to obtain an injunction, to block generic competition by paying its generic competitor to

refrain from coming to market. By allowing Abbott to purchase the protection from competition that Congress deliberately withheld, the Eleventh Circuit improperly substituted its judgment for that of Congress as to the proper balance between the interests of pharmaceutical patent holders and those of consumers.

If the Eleventh Circuit had correctly identified the probabilistic nature of Abbott's patent rights, it could then have determined that the Agreement bolstered the exclusionary power arising from Abbott's patent rights from a contingent right to an absolute right. It has been settled law for decades that when the patent owner exercises exclusionary power beyond that conferred by the patent, it and its coconspirators are fully subject to the antitrust law, including, where the nature of the restraint warrants, the *per se* rule. *See, e.g., United States v. New Wrinkle, Inc.*, 342 U.S. 371, 377-80 (1952) (patent pooling agreement fixing the prices at which licensees would sell patented products was beyond the patent monopoly and held *per se* illegal); *United States v. Line Material Co.*, 333 U.S. 287, 314 (1948) (price-fixing pursuant to patent cross-licenses *per se* illegal since this is more than exploitation of patents); *United States v. Masonite Corp.*, 316 U.S. 265, 282 (1942) (price-fixing by patentee and competitors through agency agreements constituted an enlargement of the limited patent grant and was therefore *per se* illegal). Here, the Agreement constitutes an express, naked horizontal territorial restraint that has long been held *per se* illegal under Section 1 of the Sherman Act. *United States v. Topco Associates*, 405 U.S. 596, 608 (1972); *Palmer v. BRG of Georgia, Inc.*, 498 U.S.

46, 49-50 (1990).[10]

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This is precisely what the Sixth Circuit determined on

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[10] *Per se* treatment is also warranted in this case because the Agreement, on its face, restrains the sale of all terazosin hydrochloride products, including non-infringing products. Pet. App. 118a ("Geneva shall not sell, offer for sale, donate, or otherwise distribute in the United States *any* Terazosin Hydrochloride Product.") (emphasis added); Pet. App. 113a (defining "Terazosin Hydrochloride Product" as "*any* pharmaceutical product, regardless of formulation or dosage form (tablet, capsule, etc.), containing terazosin hydrochloride") (emphasis added). It is axiomatic that Abbott's Hytrin patents give it the right to seek to prevent others from infringing its patent. *See* 35 U.S.C. § 271(a) (2003) (defining infringement). It is equally clear, however, that Abbott's patent rights only extend to the boundaries lawfully conferred under the patent laws. *New Wrinkle*, 342 U.S. at 378; *Masonite*, 316 U.S. at 280. Abbott's patents do not–and legally cannot–extend to Abbott the right to ban the sale of non-infringing products.

Because Abbott's patent rights cannot possibly extend to restraining the sale of non-infringing products, the territorial restraint in the Agreement clearly exceeds the scope of any rights Abbott could possibly have under its patents. Under settled Supreme Court precedent, this restraint is subject to traditional antitrust analysis, including the *per se* rule. *New Wrinkle*, 342 U.S. at 377-80; *Line Material*, 333 U.S. at 314; *Masonite*, 316 U.S. at 282. Abbott and Geneva are horizontal competitors and they have not argued that the Agreement resulted in an economic-efficiency enhancing integration, such as a joint venture, that would prevent the restraint from being analyzed as a naked agreement between competitors. Thus, the restraint in the Agreement banning all sales of terazosin hydrochloride products in the United States, whether infringing Abbott's patents or not, is a naked, horizontal territorial restraint and is *per se* illegal. *See, Topco*, 405 U.S. at 608 (holding that horizontal territorial limitations "are naked restraints of trade with no purpose except stifling competition" and are therefore "classic examples of a *per se* violation" of the antitrust laws) (internal quotation omitted).

indistinguishable facts before it. The Sixth Circuit condemned as *per se* unlawful an agreement whereby HMR paid Andrx, its generic competitor, $10 million per quarter to refrain from marketing its generic version of HMR's Cardizem. The Sixth Circuit recognized the long line of Supreme Court precedent that apply *per se* treatment to naked, horizontal restraints pertaining to prices or territories,[11] and concluded that the

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[11] The Sixth Circuit noted:

> The Supreme Court has identified certain types of restraints as subject to the *per se* rule. The classic examples are naked, horizontal restraints pertaining to prices or territories. *See, e.g.*, *NCAA*, 468 U.S. at 100, 104 S.Ct. 2948 ("Horizontal price fixing and output limitation are ordinarily condemned as a matter of law under an 'illegal *per se*' approach because the probability that these practices are anticompetitive is so high."); *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768, 104 S.Ct. 2731, 81 L.Ed.2d 628 (1984) ("Certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal *per se* without inquiry into the harm it has actually caused."); *United States v. Topco Assocs.*, 405 U.S. 596, 608, 92 S.Ct. 1126, 31 L.Ed.2d 515 (1972) ("One of the classic examples of a *per se* violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition. Such concerted action is usually termed a 'horizontal' restraint, in contradistinction to combinations of persons at different levels of the market structure, e.g., manufacturers and distributors, which are termed 'vertical' restraints. This Court has reiterated time and time again that horizontal territorial limitations ... are naked restraints of trade with no purpose except stifling of competition. Such limitations are *per se* violations of the Sherman Act." (internal citations omitted)); *Northern Pacific Ry.*, 356 U.S. at 5, 78 S.Ct. 514 ("Among the practices which the courts have heretofore deemed to be unlawful in and of themselves are price fixing, division of markets, group boycotts, and tying

agreement between HMR and Andrx was, like those cited in the long line of Supreme Court precedent, "at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the United States, a classic example of a *per se* illegal restraint of trade." Pet. App. 95a.

In reaching its conclusion, the Sixth Circuit rejected defendants' argument that HMR'S patent rights gave it an absolute right to exclude its competitors. The Court observed that there was no "'impenetrable' legal impediment to Andrx's production and sale of its FDA-approved generic product". Pet. App. 108a. Indeed, the Court noted that if the "independent durability of [HMR's] patent and the validity of its infringement claim" had been sufficient on their own to exclude Andrx from the market, then HMR "would not have paid [Andrx] $89 million to effect what the patent and infringement suit had already accomplished." Pet. App. 109a. Rather than granting to HMR an absolute right to exclusion, the patent law and HMR's patent merely created in Andrx a fear of damages in the patent infringement litigation, a fear that may or may not have prompted Andrx, acting "unilaterally (and legally) [to refrain from bringing] its generic" product to market. Pet. App. 104a. HMR's payments to Andrx gave to HMR that which the patent law did not: "the Agreement *guaranteed* to HMR that its only potential competitor at that time, Andrx, would, for the price of $10 million per quarter, refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval." Pet. App. 94a (emphasis added).

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arrangements." (internal citations omitted)).

Pet. App. 93a-94a.

The Sixth Circuit held that HMR did not procure Andrx's exclusion from the market merely by exercising the statutorily-approved exclusionary power of the patent. Instead, HMR procured Andrx's exclusion *by bolstering* the exclusionary power with $89 million. The Sixth Circuit held: "[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." Pet. App. 95a.

The Eleventh Circuit specifically recognized the circuit split on this issue:

> We recognize that the Sixth Circuit appeared to take the opposite view in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir.2003) ( "[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competition by paying the only potential competitor $40 million per year to stay out of the market.") When the exclusionary power of a patent is implicated, however, the antitrust analysis cannot ignore the scope of the patent exclusion. "[T]he protection of the patent laws and the coverage of the antitrust laws are not separate issues." *(United States v. Studiengesellschaft kohle*, mb.h., 670 F.2d 1122, 1128 (D.C. Cir. 1981). [W]e do not think that a payment from the patentee to the alleged infringer should be automatically condemned under the antitrust laws (footnote omitted).

Pet. App. 33a.

## II. The Issue Has Been Fully Debated and is Ripe for Review

The issue of whether reverse payments should be *per se* unlawful has been the subject of thorough scholarly debate by commentators and enforcement agencies. *See, e.g.,* Keith Leffler & Cristopher Leffler, *The Probabilistic Nature of Patent Rights*, 17 Antitrust 77 (2003) (advocating for a *per se* ban on reverse payment patent settlements); Peter J. Prommer, *Note: The Pioneer and Generic Drug Manufacturer Agreements: Is the Sherman Act Big Enough to Swallow These Pills?*, 2002 J.L. Tech. & Pol'y 215 (2002)(same); Maureen O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 Minn. L. Rev. 1767 (2003)(advocating a rule of presumptive illegality). *But see, e.g.,* Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Per Se Illegal?*, 47 Antitrust Bull. 491 (2002) (rejecting *per se* treatment); Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, 17 Antitrust 68 (2003).

Prominent commentators have concluded that agreements such as that at issue here should be found to be "presumptively unlawful". *See,* Herbert Hovenkamp *et al.*, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1759 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391, 396-402 (2003). These commentators note that Congress did not, as it might have, grant patent holders the automatic right to exclude generic competition during the pendency of patent litigation or grant patents a conclusive presumption of validity. Rather, Congress permitted patent holders – if they sue in a timely way (which Abbott did not) – an exclusion up to 30 months. Otherwise,

patent holders are left to seek a preliminary injunction from a court. As a general matter, the probability of obtaining such an injunction is less than 100%. Payments by the patent holder such as those involved in this case bolster the probability of exclusion from something less than 100%, however, to 100%. Thus, such payments impermissibly add to the exclusionary power of the patent. As Professor Hovenkamp explains:

> [A] patent is not a right to exclude, but rather a right to try to exclude. Indeed, a significant number of patents that make it to court are ultimately held invalid or not infringed. The legitimate exclusion value of a pharmaceutical patent is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid. What the pharmaceutical patentees who agree to exclusion payments seek is something more -- a guaranteed insulation from competition, without the risk that the patent is held invalid. [Intellectual property] policy does not offer such a guarantee, and does not immunize from antitrust scrutiny those who seek it by entering into agreements that exclude potential competitors.

Hovenkamp, 87 Minn. L. Rev. at 1761-62.[12]

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[12] Prof. Hovenkamp proposes the following standard regarding reverse payments:

> [A] payment from a patentee to an infringement defendant for the latter's exit from the market is presumptively unlawful, shifting the burden of proof to the infringement plaintiff. The infringement plaintiff can defend by showing both (1) the ex ante

The Federal Trade Commission recently adopted a similar view. *See in In re Schering-Plough Corporation*, FTC Docket No. 9297, 2003 WL 22989651 (FTC Dec. 8, 2003) ("In re Schering-Plough") (page citations are to page numbers available on Westlaw version). Like the Sixth Circuit and Professor Hovenkamp, the FTC recognized that neither the patent law nor the Hatch-Waxman Act grants to a patent holder an absolute right to exclusion. The FTC noted that "antitrust analysis must accept statutes and regulations as they are, and evaluate restraints in the context of the existing legal framework." *Id.* at 16. Accordingly the FTC found:

> We cannot assume that [the patent holder] had a right to exclude...generic competition for the life of the patent any more than we can assume that [the generic manufacturer] had the right to enter earlier. In fact, we make neither assumption but rather focus on the effect that [the patent holder's] payment to [the generic manufacturer] was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement.

*Id.* at 17.

The FTC held that "if there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for

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likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending to the lawsuit.

*Id.* at 1759.

the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *Id.* at 15. It held that any substantial payment made by the patent holder is therefore anticompetitive. *Id.*[13]

In sum, the scholars and regulatory agencies have fully debated the issue and it is ripe for this Court's review.

## III. The Issue Presented Is One of Great Importance

On average, the price of generic drugs is less than half that of their brand-name counterparts. Congressional Budget Office, *How Increased Competition from Generic Drugs Has*

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[13] While the FTC asserted that its analysis was one conducted under the rule of reason, it acknowledged that the label attached to such analysis is largely a question of "semantics" and that what matters is the substance of the analysis actually employed. *Id.* at 9-10 n.17. The FTC found that a "reverse payment" raises "a red flag" that distinguished such a settlement from most other patent settlements. *Id.* at 16. The FTC stated that in future cases involving reverse payments the Commission may apply a "more truncated" analysis. *Id.* The FTC proposes that if complaint counsel have made out a *prima facie* case that the agreement has anticompetitive effects, the burden is on defendants to demonstrate that the challenged provisions are justified by procompetitive benefits that are "both cognizable and plausible." *Id.* at 9. In applying this test, the FTC considered and rejected the defendants' proffer of procompetitive justifications. In particular, the FTC considered a justification that a "'cash-starved' generic may actually be able to enter earlier and more effectively if it receives some up-front support from the pioneer manufacturer." *Id.* at 19. The FTC ruled that such a justification cannot be accepted unless the defendants "explain why the [patent holder] was the best source for the necessary funds; [and] demonstrate that the up- front support actually resulted in an entry date earlier than would be expected without it." *Id.* at 20. The FTC noted that, in any event, such an alleged procompetitive justification "could not justify a payment of any amount close to the $60 million." *Id.* at 20.

*Affected Prices and Returns in the Pharmaceutical Industry*, 31 (July 1998). The Hatch-Waxman Act has been a successful tool in bringing generic pharmaceuticals to market to compete with more expensive brand name drugs. *See* Jacob S. Wharton, *"Orange Book" Listing of Patents Under the Hatch-Waxman Act*, 47 St. Louis U. L. J. 1027, 1030 (2003)(footnotes omitted) (when Hatch-Waxman was first enacted in 1984, generic drugs comprised only 19% of prescriptions filled; in 2003, generics represented 47%).

An important aspect of the Hatch-Waxman Act is the paragraph IV filings, which allow for generics to come to market if the generic company contends that the patent for the pioneer drug is invalid or will not be infringed by the proposed generic version of the drug . Indeed, generic drug companies have been very successful in infringement suits brought under the Hatch-Waxman Act. As of June 1, 2002, in infringement actions involving paragraph IV filers, generics prevailed in 73% of the cases. *Id.* at 1038 (footnote omitted).

The Eleventh Circuit opinion, by refusing to condemn reverse payments as *per se* illegal, invites brand name and generic companies to collude rather than compete. It also endangers an important check on the monopoly power conferred by patents, by encouraging brand companies to shield weak or invalid patents from judicial scrutiny by paying generic challengers to drop their challenges. Agreements such as the one between Abbott and Geneva hold obvious appeal to their participants -- the brand protects a possibly invalid patent and the generic gets paid for, essentially, doing nothing -- but it is equally obvious that competition and the public welfare are harmed. As one commentator has noted:

In normal litigation, the public trusts an alleged

> infringer to be the strongest competitor of a patent holder in favor of consumers. Generics no longer favor consumers in Hatch-Waxman settlements. Their interests diverge from consumers' interests as soon as innovators drop dollars into their pocketbooks. Effectively, generics are paid to be weak competitors. For this reason alone, public policy cannot truly support settlements stemming from Hatch-Waxman litigation.

Janet A. Gongola, *Prescriptions for Change: The Hatch-Waxman Act and New Legislation to Increase the Availability of Generic Drugs to Consumers*, 36 Ind.L.Rev. 787, 823 (2003)(footnotes omitted).

## CONCLUSION

The petition for a writ of certiorari should be granted.

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*Counsel for Petitioners*

February 16, 2004

**UNITED STATES COURT OF APPEALS**
**For the Eleventh Circuit**

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No. 02-12091

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D.C. Docket No. 99-01317-MD-PAS

VALLEY DRUG COMPANY,
LOUISIANA WHOLESALE DRUG COMPANY, INC. ET AL.

*Plaintiffs-Appellees,*

*-v.-*

GENEVA PHARMACEUTICALS, INC.
ABBOTT LABORATORIES,

*Defendants-Appellants.*

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*Appeal from the United States District Court*
*for the Southern District of Florida,*

*September 15, 2003*

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Before TJOFLAT and ANDERSON, Circuit Judges, and STAFFORD*, District Judge.

*ANDERSON, Circuit Judge:*

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* *Honorable William H. Stafford, United States District Judge for the Norther District of Florida, sitting by designation.*

This case comes to us on interlocutory appeal from the district court's order granting plaintiffs' motion for partial summary judgment. The issue with which we are presented is whether the district court properly determined that two agreements among the defendants were *per se* violations of § 1 of the Sherman Act, 15 U.S.C. § 1. Because we conclude that the district court incorrectly applied the law, the order below will be reversed and the case remanded for further proceedings consistent with this opinion.

## I. BACKGROUND

This is a private antitrust lawsuit, or rather numerous private antitrust lawsuits, brought against three pharmaceuticals manufacturers. The various cases asserting antitrust injury from the actions of the defendants have been consolidated by the Judicial Panel on Multidistrict Litigation in the Southern District of Florida. Plaintiffs basically assert that two agreements, one between defendant-appellant Abbott Laboratories ("Abbott") and defendant- appellant Geneva Pharmaceuticals ("Geneva") and another between Abbott and defendant Zenith Goldline Pharmaceuticals ("Zenith"),[1] entered into in 1998, violated the Sherman Act's prohibition against contracts in restraint of trade. Abbott, a manufacturer of the pioneer drug Hytrin, entered separate agreements with generic manufacturers Zenith and Geneva while those companies were pursuing FDA approval of generic versions of Hytrin and while embroiled in patent litigation with those companies. Because the facts of this case took place against a complex regulatory

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[1] Zenith came to a tentative settlement following the district court's order granting partial summary judgment and is not a party to this appeal.

background, we will first describe the relevant regulatory context, then the facts of the case as they appear in the current procedural posture, and then the relevant procedural history.

A. *Regulatory Framework*

No new drug can be marketed or sold in the United States without approval from the Food and Drug Administration ("FDA"). 21 U.S.C. § 355(a). Applications for FDA approval can be filed in one of two ways: as a new drug application ("NDA") under § 355(b), or as an abbreviated new drug application ("ANDA") under § 355(j). A new drug application must include exhaustive information about the drug, including reports of safety and efficacy studies. *See* 21 U.S.C. § 355(b)(1).

Prior to 1984, the NDA was the only method of obtaining FDA approval of a new drug. Every applicant had to submit safety and efficacy studies, even if such studies had already been performed for identical drugs or drugs with identical active ingredients. Adding to this inefficiency was the fact that the conduct of safety and efficacy studies would, if the new drug was the subject of a patent, constitute infringement of that patent under 35 U.S.C. § 271(a).[2] In an effort to eliminate these twin impediments to the introduction of generic drugs to the market, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act. The

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2. "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a).

primary accomplishments of the Hatch-Waxman Act were the creation of the ANDA, allowing a new drug applicant to piggyback on the safety and efficacy studies conducted for the pioneer drug, *see generally* 21 U.S.C. § 355(j); modification of the definition of infringement, so that the conduct of safety and efficacy studies for FDA approval is no longer infringing activity, *see generally* 35 U.S.C. § 271(e); and allowing the extension of patent terms to compensate for the period when a patented drug could not be marketed because it was undergoing the FDA approval process, *see generally* 35 U.S.C. § 156.

Several of Hatch-Waxman's additions to 21 U.S.C. § 355 govern FDA approval of ANDAs in the face of patent claims by pioneer drug makers. NDA applicants are required to submit the patent number and expiration date of any patent that a generic manufacturer might infringe.[3] If such a patent issues after approval of the NDA, the holder of the application is required to file the patent number and expiration date with the FDA no later than 30 days after the patent issues. *See* 21 U.S.C. § 355(c)(2). The FDA publishes this patent information, along with other information about the drug, in what is popularly known as the Orange Book. *See* 21 U.S.C. § 355(j)(7)(A).

An ANDA applicant relying on the safety and efficacy studies filed with the application of a drug listed in the Orange Book must make a certification with respect to each patent

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[3] Specifically, any patent claiming the drug of method of using the drug that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)

claiming the listed drug or a method of using the listed drug of which the applicant is aware. *See* 21 U.S.C. § 355(j)(2)(A)(vii). The applicant must certify either that (1) the patent information has not been filed with the FDA; (2) the patent is expired; (3) the patent will expire, identifying the expiration date; or (4) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug. If the applicant certifies (1) or (2), FDA approval proceeds in regular fashion, *see* 21 U.S.C. § 355(j)(5)(B)(i); if the applicant certifies (3), the application will not be approved until the date the relevant patent expires, *see* 21 U.S.C. § 355(j)(5)(B)(ii).

If the ANDA applicant certifies that the relevant patents are invalid or will not be infringed, commonly called a "paragraph IV certification," several things happen. First, the applicant must notify the patent holder. 21 U.S.C. § 355(j)(2)(B). If the patent holder brings suit for patent infringement [4] within forty-five days of receiving this notice, the FDA automatically delays approval of the ANDA for thirty

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[4] It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(j)] ... for a drug claimed in a patent or the use of which is claimed in a patent ... if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug ... claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.
35 U.S.C. § 271(e)(2)(A). This definition of infringement was added by Hatch-Waxman to allow the invocation of the procedures described in the following paragraph of this opinion.

months. *See* 21 U.S.C. § 355(j)(5)(B)(iii).[5] If the court hearing the infringement action declares the patent invalid or not infringed, this automatic delay in FDA approval terminates, 21 U.S.C. § 355(j)(5)(B)(iii)(I), or, if the court finds the patent valid and infringed, the approval date will be set for a date on or after the patent's expiration, 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A). If the court grants the patent holder a preliminary injunction prior to the expiration of the 30-month stay, the application will be approved on the date on which the court later holds the patent invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(III).

The timing of FDA approval is affected by another provision of Hatch- Waxman in the event that a listed drug is subject to more than one paragraph IV certification. Approval of an ANDA that contains a paragraph IV certification is automatically delayed if another ANDA was previously filed based on the same listed drug and the previous ANDA contains a paragraph IV certification. Approval of the subsequent ANDA is delayed until 180 days after the earlier of (1) the first commercial marketing of the drug under the previous application or (2) the date a court hearing an infringement action brought against the previous filer holds the patent invalid or not infringed.[6] *See* 21 U.S.C. § 355(j)(5)(B)(iv). This

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[5] The patent holder is, of course, free to sue the applicant for infringement under 35 U.S.C. § 271(e)(2)(A) after the 45-day window expires. The 30-month stay of FDA approval, however, will not be triggered.

[6] When the agreements at issue were entered into, the FDA regulations defined the relevant court decision triggering the end of the 30-month stay or the start of the first filer's 180-day exclusivity period as the decision of the appellate court hearing the infringement action against the first filer. This rule was challenged in court and held invalid by *TorPharm Inc., v.*

delaying mechanism gives the first generic manufacturer to file a paragraph IV certification and successfully challenge the scope or validity of a patent on a pioneer drug a 180-day period during which it is the exclusive competitor of the pioneer manufacturer. This exclusivity period is a significant incentive for generic manufacturers to challenge weak or narrow drug patents.

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*Shalala,* No. 97-1925, 1997 WL 33472411, 1997 U.S. Dist. LEXIS 21983 (D.D.C. Sept. 15, 1997), *appeal withdrawn and remanded,* 1998 WL 135491, 1998 U.S.App. LEXIS 4681 (D.C.Cir. Feb. 5, 1998), *vacated on other grounds* (D.D.C. April 9, 1998) (30-month stay expires upon judgment of the district court holding the patent not infringed), and by *Mylan Pharms., Inc., v. Shalala,* 81 F.Supp.2d 30 (D.D.C.2000) (180-day exclusivity period triggered by judgment of the district court holding the patent invalid). Though the FDA was initially committed to continued adherence to the appellate judgment rule, *see* 62 Fed. Reg. 63,268 (Nov. 28, 1997), it dropped the rule following the *Mylan* decision, *see* 65 Fed. Reg. 43,233, 43,234 (July 13, 2000) (interim rule). The FDA now considers the 180-day exclusivity period to be triggered by any district court judgment holding the patent invalid, not infringed, or unenforceable, whether or not the judgment comes from the district court hearing the infringement suit against the first filer. *See Granutec, Inc., v. Shalala,* Nos. 97-1873 & 97-1874, 139 F.3d 889, 1998 WL 153410, *8-9 (4th Cir. April 3, 1998) (unpublished, table decision reported at 139 F.3d 889) (endorsing the FDA's position that, if the successful defense requirement is invalid, the court decision triggering the 180-day exclusivity period is the decision of any district court). *See also Teva Pharms., USA, Inc. v. FDA,* 182 F.3d 1003 (D.C.Cir.1999) (reversing district court's denial of an injunction to require the FDA to recognize the dismissal with prejudice of an infringement suit against a subsequent filer as triggering the first filer's 180-day exclusivity period). *See infra* at n. 12 for a discussion of the successful defense requirement.

B. *Factual History* [7]

1. Zenith's and Geneva's ANDAs

Abbott manufactures Hytrin, a brand-name drug with the active ingredient dihydrate terazosin hydrochloride.[8] Hytrin is used to treat hypertension and enlarged prostate, and has been a very successful product for Abbott. Abbott obtained FDA approval of its NDA for Hytrin in 1987 and has held a number of patents related to terazosin hydrochloride over the years. Its first patent, issued in 1977, covered the basic terazosin hydrochloride compound. *See Abbott Labs. v. Novopharm Ltd.*, Nos. 96-C-611 & 95-C-6657, 1996 WL 131498, *1 (N.D.Ill. March 15, 1996). That patent has since expired, though Abbott has been issued other patents for various crystalline forms of the compound and various methods of using and preparing the compound.

Geneva filed four ANDAs based on Hytrin between 1993 and 1996, each time making paragraph IV certifications with respect to Abbott's listed patents. Abbott brought infringement suits under 35 U.S.C. § 271(e), invoking the 30-month stay of FDA approval of Geneva's ANDAs. On April 29, 1996, Geneva filed two additional ANDAs based on Hytrin, one for a capsule form of terazosin hydrochloride and one for a tablet

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7. The facts are largely uncontested by the parties.

8. Terazosin hydrochloride is a crystal. Dihydrate terazosin hydrochloride is a particular crystalline polymorph of terazosin hydrochloride. The opinion will refer to terazosin hydrochloride and its polymorphs simply as terazosin hydrochloride unless greater specificity is appropriate.

form,[9] making paragraph IV certifications with respect to the relevant patents. Within forty-five days of receiving notice of Geneva's paragraph IV certifications, Abbott filed an infringement suit based on the submission of the tablet ANDA, asserting that the Geneva's tablet terazosin hydrochloride product infringed Abbott's Patent No. 5,504,207 ("the '207 patent").[10] In the suit, Geneva admitted infringement but contested the patent's validity. Apparently through oversight, Abbott failed to file an infringement suit based on the submission of the capsule ANDA. FDA consideration of that ANDA, therefore, proceeded unhindered, and Geneva's capsule ANDA was approved in March of 1998. When Abbott was notified of this approval, it began efforts to amend its complaint to allege that Geneva's terazosin hydrochloride capsule infringed the '207 patent.

Zenith, meanwhile, filed an ANDA for a terazosin hydrochloride drug [11]in June of 1994, making a paragraph IV certification with respect to Abbott's Hytrin patents. Abbott was issued a patent claiming forms of terazosin hydrochloride on May 2, 1995, Patent No. 5,412,095 ("the '095 patent"), and another on April 2, 1996, the '207 patent. Abbott timely filed this patent information with the FDA, which then required Zenith to amend its ANDA to make a certification with regard to these newly listed patents. Zenith resisted, hoping to avoid

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[9] The active ingredient in these two drugs is anhydrous terazosin hydrochloride.

[10] The '207 patent, issued on April 2, 1996, claims a method of preparing anhydrous terazosin hydrochloride. The patent is due to expire in October of 2014.

[11] The active ingredient of this drug is anhydrous terazosin hydrochloride.

the 30-month stay of approval and the 180-day delay of approval based on Geneva's earlier-filed ANDAs.[12] Instead of certifying, Zenith brought suit against Abbott in an attempt to force Abbott to delist its '095 and '207 patents, relieving Zenith of the obligation to certify with respect to those patents, and seeking a declaration that its terazosin hydrochloride drug did not infringe those patents. Zenith's suit alleged that Abbott listed the '095 and '207 patents knowing that the patents did not claim Hytrin or a method of using Hytrin. Abbott counterclaimed for infringement. Zenith's attempt to obtain a preliminary injunction against the listing of the patents was unsuccessful. *See Zenith Labs. v. Abbott Labs.*, No. 96-1661, 1997 U.S. Dist. LEXIS 23954 (D.N.J. Oct. 1, 1997). Zenith appealed the denial to the Federal Circuit.

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[12] Prior to 1998, the FDA applied the "successful defense" requirement to ANDA filers hoping to take advantage of the 180-day exclusivity period. A subsequently-filed ANDA would only have its approval date delayed by 180 days if the first-filer had successfully defended against an infringement suit. *See* 59 Fed. Reg. 50,338, 50,367 (Oct. 3, 1994) (adopting successful defense regulation as a final rule, codified at 21 C.F.R. § 314.107). If Zenith's ANDA were ready for approval before Geneva successfully defended Abbott's infringement suit, then the ANDA would be approved without the 180-day delay. If Zenith were forced to make a paragraph IV certification with respect to Abbott's '095 and '207 patents, however, Abbott could invoke the 30-month stay of approval, giving Geneva more time to defend Abbott's infringement action against it.

The successful defense requirement was eventually held to be an unreasonable interpretation of the Hatch-Waxman Act by two courts of appeals. *See Mova Pharm. Corp. v. Shalala,* 140 F.3d 1060, 1069-70 (D.C.Cir.1998); *Granutec,* 1998 WL 153410, at *6-7. The *Mova* court enjoined the FDA from enforcing the regulation, and the FDA dropped the requirement effective November 10, 1998. *See* 63 Fed. Reg. 59,710, 59,711 (Nov. 5, 1998) (interim rule).

2. The Agreements

The agreements challenged by the plaintiffs arose against this backdrop. On March 31, 1998, Abbott and Zenith entered an agreement dismissing Zenith's delisting claims and Abbott's infringement counterclaims ("Zenith Agreement"). In the Zenith Agreement, Zenith acknowledged the validity of each of Abbott's patents claiming terazosin hydrochloride and admitted that any terazosin hydrochloride product Zenith might market would infringe these patents. Zenith agreed not to sell or distribute any pharmaceutical product containing any form of terazosin hydrochloride until someone else introduced a generic terazosin hydrochloride product first or until Abbott's Patent No. 4,215,532 ("the '532 patent") expired.[13] Zenith agreed not to sell or transfer its rights under any ANDA application relating to a terazosin hydrochloride drug, not to aid any other person in gaining FDA approval of a terazosin hydrochloride drug, and not to aid any other person in opposing or invalidating any of Abbott's patents claiming terazosin. In return, Abbott agreed to a payment schedule according to which Abbott would pay Zenith $3 million up front, $3 million after three months, and $6 million every three months thereafter until March 1, 2000, or until the Agreement terminated by its own terms. If another generic manufacturer introduced a terazosin hydrochloride drug and obtained a 180-day exclusivity period, Abbott's payments would be halved until the period expired. Abbott agreed not to sue Zenith for infringement if it entered the market consistent with the Agreement.

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[13] The '532 patent claims dihydrate terazosin hydrochloride, the active ingredient in Hytrin. That patent expired on February 17, 2000.

Abbott entered an agreement with Geneva on April 1, 1998 ("Geneva Agreement"). According to the Geneva Agreement, Geneva agreed not to sell or distribute any pharmaceutical product containing any form of terazosin hydrochloride until either Abbott's '532 patent expired, someone else introduced a generic terazosin hydrochloride drug, or Geneva obtained a court judgment that its terazosin tablets and capsules did not infringe the '207 patent or that the patent was invalid. This latter condition required a final judgment from which no further appeal could be taken, including petition for certiorari to the Supreme Court. Geneva agreed not to transfer or sell its rights under its ANDAs, including its right to the 180-day exclusivity period. Geneva also agreed to oppose any subsequent ANDA applicant's attempt to seek approval of its application based on Geneva's failure to satisfy the then- existing successful defense requirement and to join and support any attempt by Abbott to seek an extension of the 30-month stay of FDA approval on Geneva's tablet ANDA. In return, Abbott agreed to pay Geneva $4.5 million each month until either someone else brought a generic terazosin hydrochloride product to market or Abbott won a favorable decision in the district court on its infringement claim. If Geneva won in district court, Abbott's $4.5 million monthly payments would go into escrow pending resolution of the appeal, with the escrowed funds going to the party prevailing on appeal. Abbott reserved the right to terminate its payments after February 8, 2000, if no other generic terazosin hydrochloride product had been marketed as of that date. If Abbott exercised this right, it would execute a release in Geneva's favor of any claims of infringement based on the '207 patent.

3. Termination of the Agreements

The district court hearing Abbott's infringement suit against Geneva handed down its decision on September 1, 1998. *Abbott Labs. v. Geneva Pharms., Inc.*, Nos. 96-C-3331, 96-C-5868, & 97-C-7587, 1998 WL 566884 (N.D.Ill. Sept. 1, 1998). The court held the '207 patent invalid because the crystalline form of terazosin hydrochloride claimed in the patent was on sale in the United States more than one year before Abbott applied for the patent, *see* 35 U.S.C. § 102(b). 1998 WL 566884 at *7. Abbott appealed to the Federal Circuit, which affirmed on July 1, 1999. 182 F.3d 1315 (Fed.Cir.1999). Abbott's petition for certiorari was denied on January 10, 2000. 528 U.S. 1078, 120 S.Ct. 796, 145 L.Ed.2d 671 (2000).

The Agreements did not terminate on their own terms, however. The parties terminated the Agreements on August 13, 1999, apparently in response to an FTC investigation of those Agreements. The FTC action resulted in a consent settlement. *See Matter of Abbott Labs.*, No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000), *also available at* http://www.ftc.gov/os/2000/05/c3945.do.htm.

C. *Procedural History*

All class action and individual antitrust plaintiffs filed a joint motion for summary judgment that the Agreements were *per se* illegal under § 1 of the Sherman Act on February 18, 2000. The district court issued an order granting the motion on December 13, 2000. Permission to take an interlocutory appeal from the order under 28 U.S.C. § 1292(b) was granted on April 19, 2002.

D. *The Order Granting Summary Judgment*

The December 13, 2000, Order granting plaintiffs' motion for partial summary judgment concluded that the Agreements were *per se* violations of § 1 of the Sherman Act. The Order characterized the Agreements as geographic market allocation Agreements between horizontal competitors, essentially allocating the entire United States market for terazosin drugs to Abbott, who shared its monopoly profits with the other cartel members during the life of the Agreements.

The court found that on the eve of the Agreements,

> both Geneva and Zenith were poised to market generic versions of Hytrin in the United States. Geneva received final FDA approval for its generic capsule in March subject to "validation," and the 30-month stay on its generic tablet proposal was set to expire in October. Zenith declared that it was ready to market a generic tablet upon receipt of a favorable decision from the Federal Circuit and final FDA approval.

*In re Terazosin Hydrochloride Antitrust Litig.*, 164 F.Supp.2d 1340, 1345- 46 (S.D.Fla.2000). Despite being poised to enter the market, however, "Geneva and Zenith forswore competing with Abbott in the United States market for terazosin hydrochloride drugs...." *Id.* at 1348-49.

The court identified four elements of the Agreement with Geneva that were anticompetitive: (1) Geneva's promise not to market its terazosin capsule until the Agreement terminated;

(2) Geneva's promise not to market its terazosin tablet until the Agreement terminated; (3) Geneva's promise not to sell its rights in its capsule and tablet ANDAs until the Agreement terminated; and (4) Geneva's promise to aid Abbott in opposing any attempt by other ANDA applicants to enter the market before the Agreement terminated. The court identified three anticompetitive elements of the Agreement with Zenith: (1) Zenith's agreement to dismiss its delisting suit; (2) Zenith's promise not to aid any other entity's challenge to the validity of Abbott's terazosin patents; and (3) Zenith's promise not to market a generic terazosin product until the Agreement terminated. The essence of the Agreements, the court concluded, was to "dissuade[ ] Geneva and Zenith from marketing the first generic terazosin hydrochloride drugs in the United States for an indefinite period [and] eliminat[e] the risk that either drug maker would sell or purchase the right to introduce such drugs in the interim...." *Id.* at 1349.

Despite holding the Agreements *per se* unlawful, the court nonetheless entertained, and rejected, the defendants' arguments that the Agreements were either pro-competitive or benign.[14] Defendants argued that the Agreements eliminated the "substantial legal and financial risks" that accompany market

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[14] Defendants also argued that the Agreements were immune from antitrust liability under the *Noerr-Pennington* doctrine, *see United Mine Workers v. Pennington*, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965); *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961); that the Agreements were not subject to *per se* treatment because of their novelty; and that the Agreements could not have anti-competitive effects because independent regulatory prohibitions prevented market entry by Geneva and Zenith until at least August of 1999. The court rejected these arguments, as well. The defendants do not raise their *Noerr-Pennington* or ineffective restraints arguments on appeal.

entry while patent disputes remain unresolved. This justification was rejected for three reasons. First, the Agreement with Geneva was unnecessary to avoid these risks, because Geneva's unilateral decision to forego entry would achieve the same result. Second, the Agreement with Geneva did not resolve the patent litigation; "in fact, it tended to prolong that dispute to Abbott's advantage." *Id.* at 1350. The litigation was prolonged by the provisions extending the Agreement until the patent dispute was finally resolved, including Supreme Court review, and by Geneva's promise to aid Abbott in any motion seeking to extend the 30-month stay of FDA approval of Geneva's tablet ANDA. Finally, the court rejected the argument that the provision of the Agreement permitting Geneva to enter the market if Abbott elected to suspend its payments was pro-competitive. Although the court may have been willing to "infer that this clause was a catalyst for competition if Geneva paid Abbott for it, [ ] the suggestion that Abbott handsomely paid Geneva to spur competition in its own lucrative domestic market for terazosin hydrochloride products is patently unreasonable." *Id.* at 1351. The court did not analyze any potentially efficiency-enhancing effects of the Agreement with Zenith, concluding that the Agreement "would indefinitely postpone Zenith's entry into the United States market and would permit competition only once Abbott lost its exclusive market." *Id.*

Defendants argued that because the Agreement with Geneva was analogous to an interim patent settlement and the Agreement with Zenith terminated the litigation between Zenith and Abbott, the court should treat the Agreements as patent litigation settlements. The court rejected this argument as well, concluding that the Agreement with Geneva did not resolve Abbott's infringement suit and that the termination of

litigation between Zenith and Abbott "was part of a larger scheme to restrain the domestic sale of generic terazosin hydrochloride products." *Id.* at 1353. Even if the Agreements were patent litigation settlements, the court held, such settlements were not immune from *per se* analysis. *Id.*

E. *Issues Appealed*

On appeal, Abbott and Geneva argue that the district court erred in concluding that the Agreements were *per se* violations of § 1 of the Sherman Act and that genuine issues of material fact remain in dispute.

Appellants argue that courts lack sufficient experience with agreements of the kind at issue to draw the conclusion that "history and analysis have shown that in sufficiently similar circumstances the rule of reason unequivocally results in a finding of liability." *Seagood Trading Corp. v. Jerrico, Inc.*, 924 F.2d 1555, 1567 (11th Cir.1991) (quotation and citation omitted). Appellants also argue that there are pro-competitive justifications for the Agreements that warrant analysis under the rule of reason. Appellants argue that genuine issues of material fact are in dispute with regard to these potential pro-competitive effects. Finally, Appellants argue that the Agreements are patent litigation settlements that must be analyzed under the rule of reason unless it is shown that the settlements were "sham."[15]

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[15] Indeed, all of appellants' arguments rely primarily on the circumstance that the Agreements arose in the context of patent litigation.

## II. STANDARD OF REVIEW

We review a district court's grant of summary judgment *de novo*, applying the same legal standards applied by the district court. *Bailey v. Allgas, Inc.,* 284 F.3d 1237, 1242 (11th Cir.2002). Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). We view the evidence in the light most favorable to the non-movant, resolving all reasonable doubts and drawing all reasonable inferences in that party's favor. *Bailey,* 284 F.3d at 1243.

## III. DISCUSSION

Section 1 of the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations...." 15 U.S.C. § 1. It is understood that the ban on "contract[s] in restraint of trade" means only unreasonable restraints, *State Oil Co. v. Khan,* 522 U.S. 3, 10, 118 S.Ct. 275, 279, 139 L.Ed.2d 199 (1997), that is, restraints that impair competition, *Chicago Board of Trade v. United States,* 246 U.S. 231, 238, 38 S.Ct. 242, 244, 62 L.Ed. 683 (1918). Some types of agreements are so obviously anticompetitive, or so unlikely to be pro-competitive, that such agreements can be deemed to violate the Sherman Act without much more than an examination of the agreement itself and the relationships of the parties to the agreement. *State Oil,* 522 U.S. at 10, 118 S.Ct. at 279; *Arizona v. Maricopa County Med. Soc.,* 457 U.S. 332, 344, 102 S.Ct. 2466, 2473, 73 L.Ed.2d 48

(1982). These agreements are labeled "*per se*" violations. Regardless of terminology, the ultimate purpose of the antitrust inquiry is to form a judgment with respect to the competitive significance of the restraint at issue. *NCAA v. Bd. Regents Okla. Univ.*, 468 U.S. 85, 103, 104 S.Ct. 2948, 2962, 82 L.Ed.2d 70 (1984). The analytic focus should be on what conclusions regarding the competitive impact of a challenged restraint can confidently be drawn from the facts demonstrated by the parties. *See California Dental Ass'n v. FTC*, 526 U.S. 756, 779-81, 119 S.Ct. 1604, 1617- 18, 143 L.Ed.2d 935 (1999), *NCAA*, 468 U.S. at 103-04, 104 S.Ct. at 2961-62.

The district court focused on the agreements by Geneva and Zenith not to enter the market with FDA-approved (or approval pending) generic terazosin drugs, holding that this exclusionary effect of the Agreements constituted an allocation of the market between horizontal competitors and that the Agreements were therefore *per se* illegal. We begin our discussion by addressing this exclusionary effect of the Agreements.

A.

An agreement between competitors to allocate markets is, as the district court noted, clearly anticompetitive. Such an agreement has the obvious tendency to diminish output and raise prices. When a firm pays its only potential competitor not to compete in return for a share of the profits that firm can obtain by being a monopolist, competition is reduced. *See, e.g., Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50, 111 S.Ct. 401, 403, 112 L.Ed.2d 349 (1990) (per curiam) (agreements not to compete within certain territorial limits are obviously anticompetitive); *United States v. Topco Assocs.*, 405 U.S.

596, 608, 92 S.Ct. 1126, 1133-34, 31 L.Ed.2d 515 (1972) (observing that an agreement between competitors to allocate territories is a "classic example" of a *per se* violation of the Sherman Act, with no purpose other than reducing competition).

If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order. This is not such a case, however, because one of the parties owned a patent. For reasons explained below, and in light of the fact that all parties seem to agree that the ANDAs that were the subjects of the infringement suits infringed Abbott's '207 patent, we reject the district court's characterization of the instant Agreements as illegal *per se*. We believe any such characterization is premature without further analysis of the kind suggested in this opinion. Because the market allocation characterization was central to the district court's conclusion that the Agreements in their entireties are *per se* violations of § 1 of the Sherman Act, we will reverse the grant of summary judgment.

A patent grants its owner the lawful right to exclude others. *See* 35 U.S.C. §§ 271(a) (defining infringement) & 283 (providing injunctive relief for infringement); *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215, 100 S.Ct. 2601, 2623, 65 L.Ed.2d 696 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."). This exclusionary right is granted to allow the patentee to exploit whatever degree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions. *Bonito Boats, Inc., v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51, 109 S.Ct.

971, 977-78, 103 L.Ed.2d 118 (1989); *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1127 (D.C.Cir.1981). The exclusionary right cannot be exploited in every way--patentees cannot pool their patents and fix the prices at which licensees will sell the patented article, for example, *see United States v. New Wrinkle, Inc.*, 342 U.S. 371, 72 S.Ct. 350, 96 L.Ed. 417 (1952)-- but a patentee can choose to exclude everyone from producing the patented article or can choose to be the sole supplier itself, *see, e.g., In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1328 (Fed.Cir.2000); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1209 (2d Cir.1981); or grant exclusive territorial licenses carving up the United States among its licensees, *see* 35 U.S.C. § 261. Within reason, patentees can also subdivide markets in ways other than territorial, such as by customer class. *Gen. Talking Pictures Corp. v. Western Elec. Co.*, 304 U.S. 175, 58 S.Ct. 849, 82 L.Ed. 1273, *aff'd on reh'g*, 305 U.S. 124, 59 S.Ct. 116, 83 L.Ed. 81 (1938) (approving a license restricting the licensee's sales to non-commercial customers). Such arrangements undoubtedly tend to result in lower production and higher prices of the patented article than if competition were unrestrained, but these anticompetitive tendencies do not render them in violation of the Sherman Act.

The above discussion illustrates the point that a patentee's allocation of territories is not always the kind of territorial market allocation that triggers antitrust liability, and this is so because the patent gives its owner a lawful exclusionary right. In characterizing the Agreements as territorial market allocations agreements, the district court did not consider that the '207 patent gave Abbott the right to exclude others from making, using, or selling anhydrous terazosin hydrochloride

until October of 2014, when it is due to expire.[16] To the extent that Zenith and Geneva agreed not to market admittedly infringing products before the '207 patent expired or was held invalid, the market allocation characterization is inappropriate.

Zenith's agreement not to market an infringing generic terazosin hydrochloride drug terminated, by its own terms, when either another generic manufacturer marketed a terazosin product and any exclusivity period expired or Abbott's '532 patent expired in February of 2000. The effect of the Zenith Agreement on the production of Zenith's infringing terazosin product appears to be no broader than the potential exclusionary effect of the '207 patent, and was actually narrower to the extent it permitted Zenith to market its drug before the '207 patent expired. Geneva's agreement not to market an infringing terazosin product terminated at the earliest of (1) a final, unappealable judgment holding the '207 patent invalid; (2) the marketing of a terazosin product by another generic manufacturer; or (3) the expiration of the '532 patent. The effect of the Geneva Agreement on the production of Geneva's infringing generic terazosin product may have been no broader than the potential exclusionary effect of the '207 patent. The '207 patent may have allowed Abbott to obtain preliminary injunctive relief or a stay of an adverse judgment pending appeal, which also would have prevented Geneva from marketing its terazosin hydrochloride products during this

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[16] The '207 patent was, of course, declared invalid on September 1, 1998, a judgment affirmed on January 10, 2000. The antitrust consequences of this subsequent invalidation will be addressed below.

period. [17]

With respect to the foregoing aspects of the two Agreements' exclusionary effects, which were the foundation of the district court's characterization of the Agreements as market allocation agreements, these are at the heart of the patent right and cannot trigger the *per se* label. [18] Unlike some kinds of agreements that are *per se* illegal whether engaged in by patentees or anyone else, such as tying or price-fixing, the exclusion of infringing competition is the essence of the patent grant. As one court has concluded, "when patents are involved ... the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is *per se* illegal." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d 188, 249 (E.D.N.Y.2003).

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[17] We say "may" because we do not hold that the '207 patent *would* have allowed Abbott to obtain a preliminary injunction or a stay of an adverse judgment pending appeal. We mean only that these are among the considerations that the district court should address on remand. We do note that appellees have not at this stage argued that Abbott would have been unable to obtain such relief.

[18] Appellees argue that the Agreements have broader exclusionary tendencies in that they also prohibited the marketing of non-infringing terazosin products, prohibited Geneva from marketing infringing products beyond the date a district court held the '207 patent invalid, and prohibited Geneva from waiving its 180-day exclusivity period. As we explain below, these prohibitions may be beyond the scope of Abbott's lawful right to exclude and, if so, would expose appellants to antitrust liability for any actual exclusionary effects resulting from these provisions that appellees can prove at the causation and damages stages of litigation. Our point thus far is that appellees have failed to prove that appellants should face *per se* antitrust liability for treble damages for the failure of Zenith and Geneva to market admittedly infringing products when no court had declared Abbott's patent invalid or unenforceable at the time of the Agreements.

Because the district court failed to consider the exclusionary power of Abbott's patent in its antitrust analysis, its rationale was flawed and its conclusion that these Agreements constitute *per se* violations of the antitrust laws must be reversed.

While our holding at this early stage of the litigation is appropriately narrow, the decision below and the arguments of the parties invite our discussion of several matters that promise to be relevant on remand. We first discuss appellees' argument that the antitrust analysis need not consider Abbott's patent rights because the '207 patent was declared invalid. We then discuss appellees' argument that the lawful right of exclusion does not include the right to pay competitors not to produce infringing products. Finally, we offer several observations with respect to the framework to be developed on remand for deciding the appropriate antitrust analysis.

B.

The individual Sherman Act plaintiffs-appellees argue that because the '207 patent was declared invalid after the Agreements were entered into, Abbott never had any patent rights and our antitrust analysis need not consider the '207 patent. We reject the appellees' argument that the agreements by Geneva and Zenith not to produce infringing products are subject to *per se* condemnation and treble-damages liability merely because the '207 patent was subsequently declared invalid. We begin with the proposition that the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into. *Polk Bros. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir.1985); *SCM Corp.*, 645 F.2d at 1207. At the time the Agreements were entered into, no court had declared Abbott's '207 patent invalid, and the

appellees have advanced no argument other than mere invalidity.[19] We hold that the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis.

The right of exclusion conferred by a patent has been characterized as a defense to an antitrust claim, *see Walker Process Equip., Inc., v. Food Mach. & Chem. Corp.,* 382 U.S. 172, 179, 86 S.Ct. 347, 351, 15 L.Ed.2d 247 (1965) (Harlan, J., concurring), or as a limited exception to the general rule that markets should be free from barriers to competition, *see id.,* 382 U.S. at 176, 86 S.Ct. at 350; *United States v. Line Material Co.,* 333 U.S. 287, 309, 68 S.Ct. 550, 561, 92 L.Ed. 701 (1948); *id.,* 333 U.S. at 310, 68 S.Ct. at 562. Appellees' argument implies that this defense is unavailable with respect to the Agreements because the '207 patent was subsequently held invalid.

The only time the Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced, it held that the antitrust claimant must prove that the patentee enforced a patent with the knowledge that the patent was procured by fraud on the Patent Office. *Walker Process,* 382 U.S. at 177, 86 S.Ct. at 350 (considering a monopolization claim against a patentee for suing to enforce a patent allegedly procured by fraud). Good faith procurement furnishes a complete defense to the antitrust claim. *Id.* Justice Harlan's concurrence explained that the effect of antitrust

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[19] That is, appellees have neither alleged nor asserted that the patent was procured by fraud, that appellants knew the patent was invalid, that there was no objective basis to believe that the patent was valid, or any such similar allegations. We therefore are not called upon to decide what the antitrust consequences of such circumstances might be.

liability on the incentives for innovation and disclosure created by the patent regime must be taken into account when a court considers whether a patentee is stripped of its immunity from the antitrust laws:

> It is well also to recognize the rationale underlying this decision, aimed of course at achieving a suitable accommodation in this area between the differing policies of the patent and antitrust laws. To hold, as we do, that private suits may be instituted under § 4 of the Clayton Act to recover damages for Sherman Act monopolization knowingly practiced under the guise of a patent procured by deliberate fraud, cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure. Hence, as to this class of improper patent monopolies, antitrust remedies should be allowed room for full play. On the other hand, to hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits. Hence, this private antitrust remedy should not be deemed to reach § 2 monopolies carried on under a nonfraudulently procured patent.

382 U.S. at 179-80, 86 S.Ct. at 351-52. This approach is commonly used by courts considering the intersection of patent law and antitrust law. *See, e.g., SCM Corp.*, 645 F.2d at 1203-06 (considering antitrust claims against a patentee for acquiring and refusing to license various patents); *Handgards, Inc., v. Ethicon, Inc.*, 601 F.2d 986, 992-93 (9th Cir.1979) (considering a monopolization claim against a patentee for asserting a patent it allegedly knew to be invalid). A suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system is required by the complementary objectives of the two:

> It is commonly said ... that the patent and antitrust laws necessarily clash ... At the same time, the two regimes seek the same object: the welfare of the public ... [ A]ntitrust law forbids certain agreements tending to restrict output and elevate prices and profits above the competitive level. Patent law also serves the interests of consumers by protecting invention against prompt imitation in order to encourage more innovation than would otherwise occur.

H. Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application, ¶ 1780a (1999) ("Hovenkamp") (citations and quotations omitted). *See also* D. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 Fla. L. Rev. 747, 748 n. 1 (2002) ("It is generally recognized that antitrust and patent law, although polar opposites in their treatment of monopolies, share common objectives."); *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1352 (Fed.Cir.1999) ("The patent and antitrust laws are complementary in purpose

in that they each promote innovation and competition ....") (citation omitted).

Employing this approach, we conclude that exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives. Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.[20] This uncertainty, coupled with a treble damages penalty, would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer is certain to lose. By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation. *See Ciprofloxacin,* 261 F.Supp.2d at 256 (expressing concern for the effect of settlement-restricting antitrust liability rules on the incentives for research and

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[20] The cost and complexity of most patent litigation is a familiar problem to the court system. *See, e.g., Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 331-32 & 334-38, 91 S.Ct. 1434, 1444 & 1445-48, 28 L.Ed.2d 788 (1971); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1475-76 (Fed.Cir.1998) (Rader, J., dissenting) (discussing claim construction); *Matter of Schering-Plough Corp.*, No. 9297, 2002 WL 1488085, *166-67 & *239-40 (F.T.C. June 27, 2002), *also available at* http://www.ftc.gov/os/caselist/d9297.htm. *See also* Crane, 54 Fla. L. Rev. at 757. The cost savings of settlement, both to the parties and to the public, are equally widely-recognized. *See Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir.1976) ("Public policy favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming.").

development); *cf. Walker Process,* 382 U.S. at 180, 86 S.Ct. at 352 (Harlan, J., concurring) (permitting antitrust liability based on a showing that mere invalidity "might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damages suits").

There may be circumstances under which the unreasonableness of a settlement agreement regarding a subsequently-invalidated or unenforceable patent would be sufficiently apparent that antitrust liability would not undermine the encouragement of genuine invention and disclosure. *Cf. Walker Process,* 382 U.S. at 179-80, 86 S.Ct. at 351 (Harlan, J., concurring) (noting that exposing patentees to antitrust liability for the assertion of a patent known to have been procured by fraud "cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure"). In this regard we note that some lower courts have extended *Walker Process* to permit antitrust claims against patentees for the anticompetitive effects of infringement lawsuits when the antitrust claimant proves that the patentee knew that the patent was invalid, *Handgards,* 601 F.2d at 994-96, or knew that the patent was not infringed, *Loctite Corp. v. Ultraseal Ltd.,* 781 F.2d 861, 876-77 (Fed.Cir.1985), *overruled on other grounds by Nobelpharma AB v. Implant Innovations, Inc.,* 141 F.3d 1059 (Fed.Cir.1998).[21] To the extent that the appellees have demonstrated nothing more than subsequent invalidity, we hold

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[21] Similarly, it has been suggested that the "sham" exception to the antitrust immunity afforded by the *Noerr-Pennington* doctrine is or may be available also to antitrust plaintiffs seeking to pierce the patent immunity. *See In re Indep. Serv. Orgs. Antitrust Litig.,* 203 F.3d 1322, 1326-27 (Fed.Cir.2000). Because the parties have not briefed such potential exceptions to the patent immunity from antitrust liability, we do not address them at this time.

that this alone is insufficient to render the patent's potential exclusionary effects irrelevant to the antitrust analysis.

C.

The class action plaintiffs-appellees argue that the patent right does not include the right to pay infringers, with the implication that any exclusion resulting from payment rather than judicial enforcement is not protected from *per se* antitrust liability by the patent laws. Our discussion with regard to the important role played by settlement in the enforcement of patent rights leads us to reject this argument as well. Appellees have not explained why a monetary payment as part of a patent litigation settlement should be flatly prohibited as a *per se* violation, particularly where the alleged infringer has not yet caused the patentee any harm and the patentee does not have a damages claim to bargain with. *See Ciprofloxacin,* 261 F.Supp.2d at 251-52 (discussing the asymmetries of litigation risk created by Hatch-Waxman and rejecting the argument that payments from the patentee to the infringer are subject to *per se* antitrust analysis); Crane, 54 Fla. L. Rev. at 774 (discussing the dynamics of settlement before the alleged infringer has entered the market).

We cannot conclude that the exclusionary effects of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the '207 patent merely because Abbott paid Geneva and Zenith in return for their respective agreements. If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the exclusionary effect,

and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement. *See Aro Corp.*, 531 F.2d at 1372. To hold that an ostensibly reasonable settlement of patent litigation gives rise to *per se* antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally. We are not persuaded that such a *per se* rule would be an appropriate accommodation of the competing policies of the patent and antitrust laws.

It may be that the size of the payment to refrain from competing, sometimes called a "reverse payment" or an "exit payment," raises the suspicion that the parties lacked faith in the validity of the patent, [22] particularly when those payments are non-refundable in the event that the patentee prevails on the infringement claim (as a bond posted as part of a preliminary injunction would be). However, in the instant case and given the state of the current record, it is difficult to infer from the size of the payments alone that the infringement suits lacked merit. We do not know, for example, what lost profits Abbott expected from generic competition or what profits Geneva and Zenith expected to gain from entry, the risk of the defendants' inability to satisfy a judgment, or the litigation costs each side expected to save from settlement. We do not know how much of the payment might have been in exchange for provisions of the Agreements other than Zenith's and Geneva's

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[22] For example, the size of the payments might be evidence supporting a claim that the patentee knew that the patent was procured by fraud, or knew that the patent was invalid, or that there was no objective basis to believe the patent was valid. *See* discussion in Part B, *supra*.

acknowledgment of validity.[23] Without these facts we cannot confidently draw the conclusion, merely from the size of the payments, that there were no genuine disputes over the validity of the patent. Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement. *See, e.g., Ciprofloxacin Hydrochloride,* 261 F.Supp.2d at 196, 234 (settlement agreements under which a patentee paid an infringer $49.1 million to acknowledge the validity of a patent, and at least $398 million for the infringer to remain off the market, though the patent was subsequently approved by the PTO on reexamination and unsuccessfully challenged in court three times).

Another possibly suspicious characteristic of the payments to Geneva is their structure (*i.e.,* tying their duration to the length of the litigation), which, as the district court noted, may have given Geneva an incentive to delay resolution of the infringement suit.[24] But if the payments were in furtherance of

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[23] For example, it seems reasonable to assume that part of the payments to Geneva were in return for Geneva's agreement not to waive its 180-day exclusivity period. Payments for provisions other than the acknowledgment of validity would not shed light on the parties' evaluations of the merits of the validity issue.

For example, it seems reasonable to assume that part of the payments to Geneva were in return for Geneva's agreement not to waive its 180-day exclusivity period. Payments for provisions other than the acknowledgment of validity would not shed light on the parties' evaluations of the merits of the validity issue.

[24] Neither appellees nor the district court have offered any similar suspicions with regard to the structure of payments under the Zenith Agreement.

the seemingly reasonable purpose of compensating Geneva for any lost profits during the course of litigation (much like a bond posted as part of a preliminary injunction), it is difficult to imagine how else to structure the payments but by tying them to the length of the litigation.

We recognize that the Sixth Circuit appeared to take the opposite view in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir.2003) ( "[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competition by paying the only potential competitor $40 million per year to stay out of the market.").[25] When the exclusionary power of a patent is implicated, however, the antitrust analysis cannot ignore the scope of the patent exclusion. "[T]he protection of the patent laws and the coverage of the antitrust laws are not separate issues." *Studiengesellschaft,* 670 F.2d at 1128. As the above discussion indicates, we do not think that a payment from the patentee to the alleged infringer should be automatically condemned under the antitrust laws,[26] nor do we

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25. The terms of the agreements at issue in the *Cardizem CD* case were similar to the terms of the Agreements in this case.

26. The Sixth Circuit seems to have placed considerable reliance upon the generic's agreement to delay entering the market in exchange for exit payments, although it may also have been influenced by other provisions of the agreement which might more readily seem to exceed the potential exclusionary power of the patent. For example, the Sixth Circuit mentioned the effect of the agreements regarding the 180-day exclusivity period as well, and its reference to the district court opinion in that case might reflect some reliance on the restriction on non-infringing products. *See Cardizem CD,* 332 F.3d at 907-08; *In re Cardizem CD Antitrust Litig.*, 105 F.Supp.2d 682, 705 (E.D.Mich.2000). However, the Sixth Circuit opinion did not

think that the evidence regarding the exit payments in this case allows a confident conclusion to be drawn at this stage of the litigation that the exclusionary effect of the Agreements were bolstered by the exit payments to a degree that exceeds the potential exclusionary power of the patent.

Because these matters were given scant attention in the district court, considering the court's primary conclusion that the Agreements were market division agreements like those in *Palmer* and *Topco,* these questions have not been explored. We simply note them here to explain our conclusion that the presence of an exit payment as part of the settlement does not alone demonstrate that the Agreements had obvious anticompetitive tendencies above and beyond Abbott's potential exclusionary rights under the '207 patent.

D.

Our discussion so far has been limited to the exclusionary effects of the instant Agreements to delay entrance into the market, the subsequent invalidation of the patent, and the mere fact of exit payments. To the extent that these or other effects of the Agreements are within the scope of the exclusionary

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purport to measure the several provisions against the exclusionary power of the patent, or differentiate between provisions that fell within the scope of the patent's protection and those which did not. *Cf. Cardizem CD,* 105 F.Supp.2d at 701 ("The anticompetitive effects of [the] patent are likewise not at issue."). To the extent that the Sixth Circuit suggests that a settlement of patent litigation was a *per se* violation of the antitrust laws merely because it involves a generic's agreement to delay marketing until resolution of the patent infringement case in exchange for exit payments, we respectfully disagree. We believe that the potential exclusionary power of the patent must first be considered.

potential of the patent, such effects are not subject to *per se* antitrust condemnation.[27] From the preceding discussion, we conclude that deciding the antitrust implications of these exclusionary effects requires an analysis of the effects of antitrust liability on the innovation and disclosure incentives created by the patent regime, with the aim of "achieving a suitable accommodation between the differing policies." *Walker Process,* 382 U.S. at 179, 86 S.Ct. at 351 (Harlan, J., concurring).

As alluded to earlier, however, *see supra* at 1306 n. 18, the instant Agreements are not confined to matters involving restrictions on infringing products, exit payments, and a subsequent court decision declaring the patent invalid. Appellees also challenge other provisions of the Agreements, such as those prohibiting the marketing of "any" generic terazosin product; Geneva's agreement not to waive its 180-day exclusivity period; and Geneva's agreement not to come to market until a final, unappealable judgment of invalidity rather than on a district court judgment. These arguments require consideration of the scope of the exclusionary potential of the patent, the extent to which these provisions of the Agreements exceed that scope, and the anticompetitive effects thereof. Because these considerations require a different analytic framework than that applied by the district court and advocated by the parties on appeal, it is appropriate to remand to the

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[27] Application of rule of reason analysis is similarly inappropriate, as the anticompetitive effects of exclusion cannot be seriously debated. Rule of reason and *per se* analysis are both aimed at assessing the anticompetitive effects of particular conduct; what is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects.

district court to apply an appropriate framework derived from this decision, and the arguments of the parties and the facts developed on remand. To aid in the development of an appropriate framework, we offer the following observations.

We recognize the patent exception to antitrust liability, but also recognize that the exception is limited by the terms of the patent and the statutory rights granted the patentee. "[T]he precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise." *Line Material,* 333 U.S. at 300, 68 S.Ct. at 557. *See also New Wrinkle,* 342 U.S. at 378, 72 S.Ct. at 353 ("Patents give no protection from the prohibitions of the Sherman Act to [price fixing] when the licenses are used, as here, in the scheme to restrain."); *United States v. Masonite Corp.,* 316 U.S. 265, 277, 62 S.Ct. 1070, 1077, 86 L.Ed. 1461 (1942) ("The owner of a patent cannot extend his statutory grant by contract or agreement. A patent affords no immunity for a monopoly not fairly or plainly within the grant.").

The appropriate analysis on remand will likely require an identification of the protection afforded by the patents and the relevant law [28] and consideration of the extent to which the Agreements reflect a reasonable implementation of these. Appellants, for example, contend that certain provisions of the Geneva Agreement are analogous to a consensual preliminary injunction and stay of judgment pending appeal. To evaluate this claim, the provisions of this Agreement should be compared to the protections afforded by the preliminary

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[28] We express no view at this time on what role the FDA's regulation of market entry might play in the appropriate antitrust analysis.

injunction and stay mechanisms and considered in light of the likelihood of Abbott's obtaining such protections. *Cf.* Hovenkamp at ¶ 2046 ("some care must be taken to ensure that ... the settlement ... is not more anticompetitive than a likely outcome of the litigation").

Any provisions of the Agreements found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act.[29] *Standard Oil Co., Ind., v. United States,* 283 U.S. 163, 175, 51 S.Ct. 421, 425-26, 75 L.Ed. 926 (1931) (recognizing that cross-licensing agreements and a division of royalties could be used to monopolize or fix prices and examining the evidence to assess the potential for anticompetitive effects as a result of the agreements at issue). The appropriate analysis of the market effects of such provisions may depend on the nature of the provision challenged. It may be that some challenged provisions are so obviously anticompetitive that they can be condemned as illegal on the evidence so far adduced, or it may be that the tendencies of some challenged provisions cannot be confidently predicted without further inquiry.

> [T]here is generally no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive

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[29] Courts have not hesitated to apply traditional antitrust principles to agreements not within the scope of the patent protection. *See Line Material,* 333 U.S. at 307, 68 S.Ct. at 560 (holding a patent pooling agreement that fixed the prices at which licensees would sell the patented product *per se* illegal); *Masonite,* 316 U.S. at 274, 62 S.Ct. at 1076 (holding a price-fixing agreement among patentees and their licensees *per se* illegal).

> effect and those that call for more detailed treatment. What is required, rather, is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint.

*Cal. Dental,* 526 U.S. at 780-81, 119 S.Ct. at 1618.[30] If on remand the court should conclude that part, but not all, of the provisions of the Agreements violate the Sherman Act, it may also be helpful to identify with specificity which provisions or combination of provisions are illegal [31] and the nature of the anticompetitive effects of those provisions or combinations in order to aid subsequent determinations on causation and antitrust injury. Finally, the particular circumstances of this case and the arguments of the parties on remand may demonstrate other relevant considerations.

IV. CONCLUSION

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[30] Because the appellants' arguments supporting the application of the rule of reason rely primarily on the circumstance that the Agreements arise out of patent litigation, and because the determination of the appropriate analysis should await the inquiries to be made on remand, we decline at this time to address the issue further. We note, however, that the application of the rule of reason is not synonymous with exhaustive factual inquiry. "[S]ome rule-of-reason cases can be disposed of merely on the basis of the parties' arguments and, more often, on the basis of a limited summary judgment record." Hovenkamp, ¶ 1508.

[31] This is not to suggest that the provisions should be considered in isolation; agreements that are anticompetitive when considered in isolation (such as covenants not to compete) can still be lawful if they are ancillary to another agreement and, when viewed in combination, will have the overall effect of enhancing competition. *See Business Elecs. Corp. v. Sharp Elecs. Corp.,* 485 U.S. 717, 729, 108 S.Ct. 1515, 1523 & n. 3, 99 L.Ed.2d 808 (1988), *Polk Bros.,* 776 F.2d at 189. We simply suggest that careful consideration of individual provisions may be helpful should it appear that the Agreements are unlawful only in part.

The district court's order granting partial summary judgment is REVERSED and this case is REMANDED for further proceedings consistent with this opinion. [32]

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[32] All pending motions are DENIED.

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE ELEVENTH CIRCUIT**

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No. 02-12091-JJ

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VALLEY DRUG COMPANY
LOUISIANA WHOLESALE DRUG CO., INC., ET AL
Plaintiff-Appellees,

versus

GENEVA PHARMACEUTICALS, INC.,
ABBOTT LABORATORIES,
Defendants-Appellants.

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On Appeal from the United States District Court for the Southern District of Florida

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ON PETITION(S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC
(Opinion _____, 11th Cir., 19___, _____F.2d _____).

Before: TJOFLAT and ANDERSON, Circuit Judges, and STAFFORD*, District Judge.

PER CURIAM:

The Petition(s) for Rehearing are DENIED and no Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules

of Appellate Procedure), the Petition(s) for Rehearing En Banc are DENIED.
ENTERED FOR THE COURT:

S/
UNITED STATES CIRCUIT JUDGE

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF FLORIDA**
**SOUTHERN DIVISION**

CASE NO. 99-MDL-1317-SEITZ/GARBER
ALL SHERMAN ACT CASES

In re TERAZOSIN HYDROCHLORIDE
ANTITRUST LITIGATION

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***ORDER GRANTING PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AND DENYING DEFENDANT ZENITH'S MOTION FOR SUMMARY JUDGMENT***

SEITZ, District Judge.

After defendant Zenith Goldline Pharmaceuticals, Inc. ["Zenith"] moved for summary judgment on the plaintiffs' federal antitrust complaints [D.E. No. 77, Civ. No. 98-3125; D.E. No. 45, Civ. No. 99-1938], the Sherman Act Plaintiffs [1] sought a partial summary judgment [D.E. No. 21, Civ. No. 99-MDL-1317] that defendant Abbott Laboratories ["Abbott"] contracted with defendants Zenith and Geneva Pharmaceuticals, Inc. ["Geneva"], to secure the entire domestic market for prescription drugs containing terazosin hydrochloride in violation of section one of the Sherman Antitrust Act, 15 U.S.C. § 1. The undisputed facts in this case

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[1] The term "Sherman Act Plaintiffs" refers to all plaintiffs who allege violations of the Sherman Antitrust Act in the individual and class cases consolidated before the Court.

demonstrate that Abbott's agreements with its horizontal competitors would tend to impair domestic competition and restrain the trade of terazosin hydrochloride products. American courts have long condemned such agreements as illegal *per se* under the Sherman Act. Accordingly, the Court will grant the requested partial summary judgment to the plaintiffs, deny defendant Zenith's motion for summary judgment without prejudice, and allow the parties to conduct full discovery on the issues of causation and damages.

## BACKGROUND

### 1. Stirrings of a Competitive Market for Terazosin Hydrochloride

Abbott developed terazosin hydrochloride for the treatment of hypertension and enlarged prostate and sought the Food and Drug Administration's ["FDA"] approval to market the drug by filing a New Drug Application ["NDA"]. Pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-91 ["FDCA"], FDA examined terazosin hydrochloride's safety and efficacy and approved it for human consumption, publishing three of Abbott's claimed patents in the publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," affectionately known as the "Orange Book."

In 1987, Abbott began exclusively marketing terazosin hydrochloride under the trademark "Hytrin" in tablet and capsule forms. Hytrin has been lucrative for Abbott. According to the Federal Trade Commission, Hytrin generated $540 million in sales in 1998, accounting for more than twenty percent of Abbott's net sales of pharmaceutical products in the

United States. [2]

Beginning in 1990, generic drug maker Geneva took steps to compete with Abbott by developing a generic terazosin hydrochloride drug that could contain different inactive ingredients and be sold without a brand name in tablet and capsule forms. Taking advantage of the "Hatch-Waxman Amendments" to FDCA that streamlined the evaluation process for proposed generic drugs,[3] Geneva applied for FDA approval by submitting four Abbreviated New Drug Applications ["ANDAs"] between 1993 and 1996. Geneva's ANDAs relied on data concerning Hytrin's safety and efficacy, asserted that the proposed generic drug was "bioequivalent" to Hytrin, and certified under paragraph IV of 21 U.S.C. § 355(j)(2)(A)(vii) that the proposed drug did not infringe any *valid* patent claimed by Abbott for Hytrin.

When Abbott received notice of Geneva's "paragraph IV

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[2] (*See Compl., Abbott Labs.*, No. C-3945, at ¶ 10 (FTC May 22, 2000), *available at* http://www.ftc.gov/os/2000/05/abbottgenevacomp.htm *and reprinted in* Zenith Notice, Ex. B, Civ. No. 99-MDL-1317, Mar. 20, 2000); *see also* FEDERAL TRADE COMMISSION, ANALYSIS TO AID PUBLIC COMMENT (2000), *available at* http://www.ftc.gov/os/2000/05/abbottgenevaanalysis.htm ["ANALYSIS"]. The Federal Trade Commission recently concluded an investigation into the Abbott-Geneva accord by entering a consent decree prohibiting similar accords. *See* ANALYSIS ¶ 21. That decree does not govern the Court's decision.

[3] Drug Price Competition & Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355). The declared purpose of this legislation was to "make available more low cost generic drugs." H.R. REP. NO. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647.

certifications" challenging its patents, it exercised its statutory right to sue Geneva within forty-five days for patent infringement under 21 U.S.C. § 355(j)(5)(B)(iii) by instituting several actions in the United States District Court for the Northern District of Illinois. By statute, these suits effectively prevented FDA from approving Geneva's disputed ANDAs for 30 months unless Abbott's Hytrin patents were declared "invalid or not infringed." *Id.* § 355(j)(5)(B)(iii)(I).

The Hatch-Waxman Amendments to FDCA furnished a significant incentive for Geneva to raise the first challenge to Abbott's Hytrin patents, namely, exclusive marketing rights to the first generic version of Hytrin for 180 days. *Id.* § 355(j)(5)(B)(iv). Under the "successful defense" regulation that FDA promulgated to implement this statutory incentive, however, Geneva needed to obtain a final decision of non-infringement from either the trial court or the Court of Appeals for the Federal Circuit in order to perfect its entitlement to the 180-day exclusive marketing period. *See* Abbreviated New Drug Application Regs., 54 Fed.Reg. 28,872, 28,894 (July 10, 1989); Abbreviated New Drug Application Regs., Patent and Exclusivity Provisions, 59 Fed.Reg. 50,338, 50,350-55 (Oct. 3, 1994). If another generic drug maker, such as Zenith, challenged Abbott's patents and successfully defended its ANDA first, Geneva would not be entitled to this statutory incentive. Zenith would be able to market the first generic terazosin hydrochloride drug, albeit without exclusive marketing rights to delay its competitors from entering the marketplace.

In June, 1994, Zenith joined the race to bring the first generic terazosin hydrochloride drug to market by filing an ANDA featuring a paragraph IV certification on one of Abbott's

Hytrin patents. (Zenith Mem., Oct. 22, 1999, Ex. 6, at 11.) Abbott brought two unsuccessful infringement suits against Zenith for infringement of this patent, which was not timely included in the Orange Book. *See Abbott Labs. v. Zenith Labs., Inc.*, 934 F.Supp. 925, 939 (N.D.Ill.1995) (dismissing case and observing that Abbott retained right to sue Zenith for patent infringement "upon the commencement of marketing ... of the generic copy"). Abbott then submitted two additional patents to FDA for inclusion in the Orange Book, U.S. Patents 5,412,095 [" '095 patent"] and 5,504,207 [" '207 patent"]. In March, 1996, FDA informed Zenith that it would have to amend its ANDA to certify with respect to those patents. Zenith balked at amending its ANDA, however, because Abbott then could institute another infringement suit and trigger a new 30-month stay of FDA approval (absent an intervening judicial determination of non-infringement) of Zenith's proposed generic tablet. On April 15, 1996, Zenith sued Abbott for improperly listing the '095 and '207 patents, and requested injunctive relief delisting them from the Orange Book. Abbott counterclaimed, alleging that Zenith had infringed those patents.

Later that month, on April 29, 1996, Geneva renewed its drive to market the first generic tablet and capsule versions of Hytrin by filing an ANDA featuring a new paragraph IV certification with respect to Abbott's recently- listed '207 patent. Abbott launched an infringement action to stop Geneva's new generic tablet proposal, but inexplicably failed to protest Geneva's new generic capsule proposal. FDA continued to evaluate the safety and efficacy of Geneva's proposed capsule while the automatic 30-month stay for approval of Geneva's proposed tablet took effect.

**2. The Survival of the "Successful Defense" Requirement**

In 1997, two federal courts rendered conflicting decisions on the validity of the successful defense requirement, temporarily throwing into question which drug maker would market the first generic version of Hytrin. On January 23rd, the United States District Court for the District of Columbia strongly questioned the validity of the successful defense regulation and concluded that the first drug maker to file an ANDA for a generic micronized glyburide product, Mova Pharmaceutical Corp., was entitled to exclusive marketing rights to that product for 180 days despite the fact that one of its competitors, Mylan Pharmaceuticals, Inc., filed a micronized glyburide ANDA later and successfully defended it first. *Mova Pharm. Corp. v. Shalala,* 955 F.Supp. 128, 131-32 (D.D.C.1997); *id* at 130 (enjoining FDA from enforcing regulation against plaintiff because underlying statute "does not include a 'successful defense' requirement"). FDA briefly ceased enforcing its regulation "in order to promote administrative uniformity and to avoid [judicial] forum shopping problems," but on July 3rd, Judge Boyle of the United States District Court for the Eastern District of North Carolina upheld the validity of the successful defense regulation and enjoined FDA from *refusing* to enforce it. *See Granutec, Inc. v. Shalala,* 1998 WL 153410, at *1 (4th Cir. Apr.3, 1998) (recounting history of unreported District Court case). The Court of Appeals for the Fourth Circuit promptly stayed this injunction pending appeal. *Id.* at *5.

On November 5, 1997, FDA announced that it would enforce the successful defense regulation and await the decision of the appellate courts before revising its standards. Policy on 180-Day Marketing Exclusivity for Drugs Marketed under

Abbreviated New Drug Applications; Clarification, 62 Fed.Reg. 63,268, 63,269 (Nov. 28, 1997). Thus, despite the decision of the United States District Court for the District of Columbia in the *Mova* case, Geneva would have to successfully defend its ANDA against Abbott's infringement suit before Zenith successfully defended its ANDA in order to market the first generic version of Hytrin.

While *Mova* and *Granutec* were pending before the federal Courts of Appeal, Zenith's campaign to beat Geneva to the market also suffered a setback. On October 1, 1997, the United States District Court for the District of New Jersey rejected Zenith's complaint for injunctive relief to delist Abbott's '095 and '207 patents, at least temporarily blocking final FDA approval of Zenith's ANDA. *See Zenith Labs., Inc. v. Abbott Labs.*, Civ. No. 96- 1661, slip. op. at 26-27 (D.N.J. Oct. 1, 1997). Zenith appealed this decision to the Court of Appeals for the Federal Circuit. Then, on February 27, 1998, Zenith asked FDA to develop "a plan of action ... to expedite final approval of Zenith's ANDA upon the delisting of Abbott's patents," so Zenith could "immediately bring [its] product to market should [it] receive a favorable court ruling." (Walgreen Pls.' Opp'n, Nov. 8, 1999, Ex. 3 (Letter from Jason A. Gross, Director, Zenith Regulatory Affairs, to Douglas L. Sporn, Director, FDA Office of Generic Drugs (Feb. 27, 1998) (previously filed under seal)).)

In late March, 1998, both Geneva and Zenith were poised to market generic versions of Hytrin in the United States. Geneva received final FDA approval for its generic capsule in

March subject to "validation,"[4] and the 30-month stay on its generic tablet proposal was set to expire in October. Zenith declared that it was ready to market a generic tablet upon receipt of a favorable decision from the Federal Circuit and final FDA approval.[5] But competition between Abbott, Geneva, and Zenith for the United States market for sales of terazosin hydrochloride drugs did not materialize.

### 3. Abbott's Accords with Zenith and Geneva

Abbott and Zenith informed the Federal Circuit on March 20, 1998, that they were settling their dispute and asked the Court to hold Zenith's appeal in abeyance. Then, on March 30th, Abbott received word that FDA had approved Geneva's generic terazosin hydrochloride capsule. During the following two days, Abbott entered into separate confidential agreements with Zenith and Geneva to alter each company's rights and responsibilities.

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[4] "Validation" refers to the process by which a drug maker produces three commercial-size batches of the approved drug to prove that its product meets the technical specifications contained in the relevant ANDA. *See* FOOD & DRUG ADMIN., GUIDELINE ON GENERAL PRINCIPLES OF PROCESS VALIDATION (1987), *reprinted in* Geneva Opp'n, Ex. 3-A, Mar. 21, 2000; *see also* 21 C.F.R. § 211.110; (Geneva Opp'n, Ex. 3, at 3 (Aff. of Joan Fiore, Geneva Project Manager)).

[5] (*See* Walgreen Pls.' Opp'n, Ex. 4 (Declaration of Karen Rocco, Associate Director, Zenith Regulatory Affairs, at ¶ 5).) According to the defendants, by filing the first ANDA on Abbott's patents, Geneva precluded Zenith from introducing the first generic version of Hytrin. (*E.g.*, Abbott Statement, Mar. 20, 2000, at 14.) This statement draws a legal conclusion and conflicts with the state of the law at the time of the defendants' agreements. *See infra* note 12 and accompanying text.

Under its March 31, 1998, "Settlement Agreement," Zenith agreed to accept $3 million to join Abbott in dismissing the disputes before the District of New Jersey and the Federal Circuit, and to accept an additional $6 million per quarter (or a prorated sum for a shorter period) to "not sell, offer for sale, donate, or otherwise commercially distribute in the United States any [t]erazosin [h]ydrochloride [p]roduct" until another drug maker sold a generic version of Hytrin in the United States, Abbott elected to "allow[ ] Zenith to enter the market," or Abbott's patents expired. (*See* Pl.'s Mem., Feb. 18, 2000, Ex. 1, at 2, 3, 5 (Zenith-Abbott Agreement (Mar. 31, 1998)) ["Zenith Agreement" or "Z.A."].) [6] Zenith also promised "not [to] aid or assist any person or entity to gain FDA approval to market a[t]erazosin [h]ydrochloride [p]roduct," and obtained Abbott's permission to market such products once generic competition began. (*Id.* at 7, 4.)

On April 1, 1998, Geneva agreed to accept $4.5 million per month from Abbott (or a prorated sum for a shorter period) to refrain from marketing any generic terazosin hydrochloride drug, including its FDA-approved capsule, until another drug maker sold a generic version of Hytrin in the United States or Geneva received a final, unappealable judgment that its proposed generic tablet did not infringe Abbott's patents. (*See* Pl.'s Mem., Ex. 2, at 2-5 (Geneva-Abbott Agreement (Apr. 1,

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[6] Zenith would receive only $3 million for the first quarter that it refrained from marketing a generic version of Hytrin, (*id.* at 3), but if Geneva ultimately enjoyed exclusive marketing rights by statute for 180 days, Abbott would pay Zenith three million dollars during that period as well. (*Id.* at 4.)

1998)) ["Geneva Agreement" or "G.A."].)[7] Geneva and Abbott agreed to continue their court battle over the proposed generic terazosin hydrochloride tablet. Geneva promised to "join and support any motion filed by Abbott ... in the Northern District of Illinois" seeking an extension of FDA's 30-month stay on approval of its proposed tablet. (*Id.* at 5.) If Geneva successfully defended Abbott's suit before the trial court, Abbott would pay subsequent monthly payments into an escrow fund payable to the final prevailing party on appeal, whether before the Federal Circuit or the Supreme Court. Geneva also pledged not to transfer the rights to its ANDAs or the FDA-approved capsule. If Abbott elected to terminate its payments in February, 2000, Geneva would enjoy the right to market terazosin hydrochloride products in the United States without objection. (*Id.* at 4.)

On April 2, 1998, and for the following sixteen months, Abbott sold the only terazosin hydrochloride drug available in the United States.

## DISCUSSION

As previously mentioned, the Sherman Act Plaintiffs seek a partial summary judgment that the defendants committed a *per se* violation of section one of the Sherman Act by contracting

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[7] Abbott reserved the right to suspend its payments to Geneva, promising "not to sue it for patent infringement ... of the '207 patent," if no drug maker introduced a generic version of Hytrin by February 18, 2000. (*Id.* at 4.) For its part, Geneva promised "to use its best efforts to oppose any attempts by any ANDA applicant that is a party to litigation involving terazosin hydrochloride patents to assert that it is entitled to approval of its ANDA ... prior to the date currently determined pursuant to 21 C.F.R. § 314.107." (*Id.* at 5.)

to allocate the United States market for terazosin hydrochloride products, thereby stifling domestic competition and restricting the output and sale of generic versions of Hytrin. The defendants counter that the challenged agreements tended to foster competition, imposed only incidental restraints on generic drug production mirroring those imposed by law, and caused no harm to the plaintiffs. Zenith, in particular, relies on these arguments and others to establish that it is entitled to summary judgment on the plaintiffs' complaints. Leaving aside the defendants' assertions regarding causation and damages until the parties have had a full opportunity to conduct discovery, [8] the Court will examine the parties' contentions *seriatim*.

**1. Summary Judgment Standard**

Summary judgment is appropriate when "the pleadings ... show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of

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[8] On February 14, 2000, the Court stayed all discovery unrelated to class issues until the parties' cross-motions for summary judgment were fully briefed and resolved. Since the parties have not conducted full discovery on the issues of causation and damages, those questions presently are not ripe for summary judgment.

Zenith protests that *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 110 S.Ct. 1884, 109 L.Ed.2d 333 (1990), bars this tribunal from considering whether the defendants committed a *per se* violation of the Sherman Act until the plaintiffs prove that they have suffered an "antitrust injury" under the Clayton Antitrust Act, 15 U.S.C. §§ 12- 37(a). As the Supreme Court observed in that case, however, "proof of a *per se* violation and of antitrust injury are distinct matters that must be shown independently." 495 U.S. at 344, 110 S.Ct. 1884 (citation omitted). Accordingly, today's decision draws no conclusion regarding whether the plaintiffs have suffered an antitrust injury.

law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). Once the moving party demonstrates the absence of a genuine issue of material fact, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.' " *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986) (quoting FED. R. CIV. P. 56(e)). Accepting this evidence as truthful, the Court must view the record and all factual inferences therefrom in the light most favorable to the non-moving party and decide whether " 'the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.' " *Allen v. Tyson Foods, Inc.*, 121 F.3d 642, 646 (11th Cir.1997) (quoting *Anderson*, 477 U.S. at 251-52, 106 S.Ct. 2505).

**2. The Sherman Antitrust Act and Illegality *Per Se***

Congress designed the Sherman Antitrust Act of 1890 as a "consumer welfare prescription" to protect free enterprise and competition. *Reiter v. Sonotone Corp.*, 442 U.S. 330, 343, 99 S.Ct. 2326, 60 L.Ed.2d 931 (1979) (citation omitted). Although section one of the Sherman Act literally bans every agreement "in restraint of trade," 15 U.S.C. § 1, this provision has been interpreted to prohibit only those contracts involving interstate commerce that "unreasonably" restrain competition. *Standard Oil Co. v. United States*, 221 U.S. 1, 55-60, 31 S.Ct. 502, 55 L.Ed. 619 (1911). Applying the "rule of reason," courts conduct an extensive and complex investigation into "the facts peculiar to the business in which the restraint is applied, the nature of the restraint and its effects, and the history of the restraint and the reasons for its adoption" to determine whether the challenged contract unreasonably restrains competition.

*United States v. Topco Assocs., Inc.*, 405 U.S. 596, 606, 92 S.Ct. 1126, 31 L.Ed.2d 515 (1972) (citation omitted). Only blatantly anti-competitive agreements that predictably "tend to restrict competition and decrease output" may be condemned as unreasonable and illegal *per se* "without elaborate inquiry as to the precise harm they have caused or the business excuse for their use." *Broadcast Music, Inc. v. Columbia Broad. Sys.*, 441 U.S. 1, 19-20, 99 S.Ct. 1551, 60 L.Ed.2d 1 (1979); *Northern Pac. Ry. Co. v. United States*, 356 U.S. 1, 5, 78 S.Ct. 514, 2 L.Ed.2d 545 (1958) (Black, J.).

**3. The Challenged Accords are Illegal *Per Se***

"[W]hether the ultimate finding is the product of a presumption or actual market analysis, the essential inquiry remains the same--whether or not the challenged restraint enhances competition." *NCAA v. Board of Regents*, 468 U.S. 85, 103, 104 S.Ct. 2948, 82 L.Ed.2d 70 (1984) (footnote omitted); *see also* 7 PHILLIP E. AREEDA, ANTITRUST LAW ¶ 1503a, at 372 (1986) ("Every antitrust suit should begin by identifying the ways in which a challenged restraint might possibly impair competition."). The defendants' agreements contain numerous covenants inimical to free enterprise.

In its agreement with Abbott, Geneva promised to withhold its FDA-approved capsule from the United States market, to refrain from selling its rights to that capsule and its tablet ANDAs, to oppose any attempts by other ANDA applicants to enter the market early, and, in the event that Geneva "successfully defended" its tablet ANDA before the Federal Circuit and secured a 180-day exclusivity period, to forgo marketing that tablet until Abbott exhausted any appeals before the Supreme Court. *See supra* pages 1346-47. Similarly, in its

accord with Abbott, Zenith agreed to dismiss its efforts to delist Abbott's Hytrin patents, to rebuff other entities' requests for help in challenging those patents, and, with the assurance of continued payment during any period of exclusivity enjoyed by a rival generic drug maker, to refrain from marketing the first generic terazosin hydrochloride product unless Abbott authorized Zenith to enter the market, or Abbott's patents elapsed. *See supra* pages 1345-46.

Viewed together and in their factual context, these provisions illustrate that Geneva and Zenith forswore competing with Abbott in the United States market for terazosin hydrochloride drugs and promised to take steps to forestall others from entering that market for the life of their respective agreements in exchange for millions of dollars in monthly or quarterly payments. Geneva and Zenith were poised to compete with Abbott at the same level of the market; Geneva had received final FDA approval for its capsule pending validation and Zenith anticipated a favorable ruling that would result in final approval of its tablet proposal. Prices were likely to fall as the output of terazosin hydrochloride drugs climbed. *See generally* 11 HERBERT HOVENKAMP, ANTITRUST LAW ¶ 1902a, at 191 (1998) ["HOVENKAMP"] (noting that horizontal agreements "enable participants to reduce the output of goods in some market, thus causing higher prices, inefficient substitutions, and the resultant losses in consumer welfare"). Instead of braving the rigors of competition, or unilaterally avoiding the arena, Geneva and Zenith both made pacts with Abbott to "enhance their collective profits to the detriment of consumers."[9] Abbott dissuaded

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[9] 7 PHILLIP E. AREEDA, ANTITRUST LAW ¶ 1503a, at 374; *see Palmer v BRG*, 498 U.S. 46, 49-50, 111 S.Ct. 401, 112 L.Ed.2d 349 (1990)

Geneva and Zenith from marketing the first generic terazosin hydrochloride drugs in the United States for an indefinite period, eliminated the risk that either drug maker would sell or purchase the right to introduce such drugs in the interim, and enlisted their potential cooperation in opposing or refusing to support other drug makers' ANDAs. This scheme of agreements clearly "den[ied] to consumers the opportunity to choose among alternative offers without offering the possibility of any joint, efficiency-producing activities." *See United States v. Realty Multi-List, Inc.*, 629 F.2d 1351, 1364 (5th Cir.1980) (citation omitted). [10] Under this scheme, the defendants would earn their profits by limiting marketwide output and maintaining a higher price for Abbott's product.

Abbott's agreements with Geneva and Zenith to forestall competition in the United States for sales of terazosin hydrochloride drugs confront the Court with "[o]ne of the classic examples of a *per se* violation"--"an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition." *Topco Assocs., Inc.*, 405 U.S. at 608, 92 S.Ct. 1126.

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(per curiam) (observing that plaintiff need not prove that defendants previously competed in relevant market to establish *per se* violation of 15 U.S.C. § 1); In re *Cardizem CD Antitrust Litig.*, 105 F.Supp.2d 618, 677-79 (E.D.Mich.2000) ["*Cardizem I* "] (same). These agreements did not deprive Geneva or Zenith of the opportunity to sell terazosin hydrochloride drugs outside the United States.

[10] In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir.1981), the Court of Appeals for the Eleventh Circuit adopted as binding precedent all decisions that the former Court of Appeals for the Fifth Circuit rendered before October 1, 1981.

> Such concerted action is usually termed a "horizontal" restraint, in contradistinction to combinations of persons at different levels of the market structure, *e.g.*, manufacturers and distributors, which are termed "vertical" restraints. This Court has reiterated time and time again that "[h]orizontal territorial limitations ... are naked restraints of trade with no purpose except stifling of competition." Such limitations are *per se* violations of the Sherman Act.

*Id.* (citations omitted); *see also id.* at 613, 92 S.Ct. 1126 (Burger, C.J., dissenting) (observing that *per se* rule rightly condemns horizontal agreements "involv[ing] restraints on interbrand competition or an allocation of markets by [an entity or group] with monopoly or near-monopoly control of the sources of supply"). *See generally* HOVENKAMP, *supra* page 11, ¶ 1902a, at 190 ("Horizontal agreements are antitrust's most 'suspect' classification.").

When presented with a plainly anti-competitive contract, the Court "need not then inquire whether the [defendants] actually possess the power to inflict public injury," or whether "the restraint ... is justified by any procompetitive purpose or effect." *Realty Multi-List,* 629 F.2d at 1362. Nevertheless, this tribunal will examine the defendants' chief mitigating arguments, mindful that "[t]he probability that anticompetitive consequences will result from a practice ... must be balanced against its pro-competitive consequences," *Arizona v. Maricopa County Med. Soc.*, 457 U.S. 332, 350 n. 16, 102 S.Ct. 2466, 73 L.Ed.2d 48 (1982), and that the defendants must "come forward with 'specific facts showing that there is a genuine issue for

trial' " on the potential consequences of their accords. *See Matsushita Elec. Indus. Co.*, 475 U.S. at 587, 106 S.Ct. 1348.

**4. The Defenses Offered by Defendants are Invalid**

The defendants claim immunity from the *per se* rule on several grounds. First, they contend that the challenged agreements tended to foster competition or had no impact on their ability to compete. Second, they argue that the agreements are beyond the scope of the *per se* rule because they were novel, analogous to patent settlements, or designed to influence government organizations. These arguments are not persuasive, and the defendants' evidence does not establish a genuine issue for trial.

**A. Economic Justifications for Challenged Accords**

**1. Pro-Competitive Motives or Provisions**

The defendants maintain that their agreements would have tended to advance competition by ending or preventing fractious patent disputes and eliminating obstacles to Geneva and Zenith's entrance into the United States market for terazosin hydrochloride products. Of course, the Supreme Court "has consistently rejected the notion that naked restraints of trade are to be tolerated because they are well intended or because they are allegedly developed to increase competition." *Topco Assocs., Inc.*, 405 U.S. at 610, 92 S.Ct. 1126 (citations omitted). Viewed in the light most favorable to the defendants, however, the record does not substantiate that the Geneva and Zenith Agreements were reasonably ancillary to pro-competitive activity rather than unreasonable restraints of trade.

The Geneva Agreement did not enhance competition. According to the defendants, Geneva contracted with Abbott to avoid "substantial legal and financial risks" accompanying the introduction of its capsule product, furthering "the public policy preference for deferring generic entry until after the resolution of any patent dispute with respect to any given drug." (Abbott Statement at 7 (citations omitted); *id.* at 13 (citing Decl. of Steven N. Wiggins, Econ. Professor, Texas A & M Univ., at ¶¶ 14-22, 32-48).) Accepting these allegations as true, it is readily apparent that Geneva did *not* have to enter into a contract with Abbott in order to defer its entry into the United States market.

Abbott's confidential agreement with Geneva did not resolve its action before the Northern District of Illinois; in fact, it tended to prolong that dispute to Abbott's advantage. Geneva agreed to accept over a million dollars per week to refrain from marketing any generic terazosin hydrochloride product until another drug maker sold a generic version of Hytrin in the United States, or it received an unappealable judgment that its proposed generic tablet did not infringe Abbott's patents. (G.A. at 3-5.) The latter condition restrained Geneva from marketing its products during the pendency of any Supreme Court review, even if Geneva obtained a favorable ruling from the Federal Circuit in satisfaction of FDA's successful defense requirement. This design did not enhance competition. [11]

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[11] *See* 59 Fed.Reg. at 50,354 ("The likelihood of an appellate court decision being heard and overruled by the Supreme Court is too remote to warrant delaying marketing and exclusivity pending resolution of a petition for writ of certiorari."). Further, Geneva also promised to "join and support any motion filed by Abbott ... in the Northern District of Illinois" seeking an extension of FDA's 30-month stay on approval of its proposed tablet, potentially delaying the proceedings even further. (G.A. at 5.)

Geneva would have been able to market terazosin hydrochloride products in the United States without objection if Abbott elected to end its payments, (G.A. at 4), but this clause cannot justify the defendants' comprehensive and unreasonable restraints. One could reasonably infer that this clause was a catalyst for competition if Geneva paid Abbott for it, but the suggestion that Abbott handsomely paid Geneva to spur competition in its own lucrative domestic market for terazosin hydrochloride products is patently unreasonable. *See* In re *Cardizem CD Antitrust Litig.*, 105 F.Supp.2d 682, 699 (E.D.Mich.2000) ["*Cardizem II* "] (concluding that drug makers' alleged agreement to allocate United States market for brand-name drug Cardizem CD provided "an incentive to stay off the market"); *Cardizem I,* 105 F.Supp.2d at 679 (noting that defendant "ignore[d] the reasonable inference that HMRI would not have paid Andrx millions of dollars to stay off the market beyond July 9, 1998, if it was not reasonably probable that Andrx would enter the market"). The Geneva Agreement clearly sought to curtail the domestic sale of generic terazosin hydrochloride drugs.

The Zenith Agreement also sought to restrain domestic competition. Zenith confidentially agreed to terminate its potentially meritorious challenge to Abbott's Hytrin patents in the District of New Jersey and the Federal Circuit in exchange for three million dollars. Thereafter, in a separate series of transactions, Zenith would receive millions of dollars to "not sell, offer for sale, donate, or otherwise commercially distribute in the United States any [t]erazosin [h]ydrochloride [p]roduct" until another drug maker sold a generic version of Hytrin in the United States, among other things. (Z.A. at 3.) Zenith also promised "not [to] aid or assist any person or entity to gain FDA approval to market a[t]erazosin [h]ydrochloride

[p]roduct," but once generic competition began, Zenith could market such products in the United States without objection from Abbott. (*Id.* at 6.) The Zenith Agreement would indefinitely postpone Zenith's entry into the United States market and would permit competition only once Abbott lost its exclusive market. Like its agreement with Geneva, Abbott's agreement with Zenith resulted in a cooperative effort to forestall competition, not to enhance it.

**2. Ineffective Restraints**

Next, the defendants contend that their agreements could not unreasonably restrain the domestic market for terazosin hydrochloride products because Geneva was unable to validate its capsule product and legally enter the market until August, 1999, and Zenith was subject to Geneva's 180-day period of exclusivity on March 31, 1998. Although the Court accepts the defendants' allegations of fact as true for purposes of resolving the plaintiffs' motion for partial summary judgment, *Allen,* 121 F.3d at 646, the contention that Zenith could not enter the market in March, 1998, draws a legal conclusion and must be disregarded by the Court under FED. R. CIV. P. 56(e). [12] Indeed, the defendants' allegations are irrelevant, for it is well-settled that

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[12] (*E.g.*, Zenith Opp'n, Mar. 20, 2000, at 5 (drawing legal conclusion)); *see Beard v. Annis,* 730 F.2d 741, 743 (11th Cir.1984) (rejecting statements of law as inadmissible); 10B Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 2738, at 346-56 (1998). The defendants' legal allegation pointedly ignores FDA's November 5, 1997, pronouncement that the agency would continue to enforce the successful defense regulation. (*See* Walgreen Pls.' Reply to Zenith, Apr. 3, 2000, at 2.) That was the state of the law on March 31, 1998.

> conspiracies under the Sherman Act are not dependent on any overt act other than the act of conspiring. It is the 'contract, combination ... or conspiracy, in restraint of trade or commerce' which § 1 of the Act strikes down, *whether the concerted activity be wholly nascent or abortive on the one hand, or successful on the other.*

*United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 224 n. 59, 60 S.Ct. 811, 84 L.Ed. 1129 (1940) (citations omitted and emphasis added); *see Maricopa County Med. Soc.*, 457 U.S. at 345, 102 S.Ct. 2466 (following *Socony-Vacuum Oil Co.* decision); *see also* AMERICAN BAR ASS'N, ANTITRUST LAW DEVELOPMENTS 79 (4th ed.1997).

**B. Similarity of Accords to Contracts Beyond the Scope of the *Per Se* Rule**

Having failed to identify a genuine issue of fact concerning the anti- competitive potential of their agreements to allocate the United States market for terazosin hydrochloride products to Abbott, the defendants attempt to redraw their accords as novel compacts, patent settlements, or petitions not subject to the *per se* rule. These efforts are also unpersuasive.

**1. Novel Agreements**

Zenith, Geneva, and Abbott assert that the impact of their agreements "is not immediately obvious" because the judiciary lacks experience with "agreement[s] between brand[ed] and generic drug manufacturers ... to settle novel delisting claims and patent litigation and [to] speed introduction of the generic ... product into the market." (Zenith Opp'n at 12; *see* Geneva

Opp'n, Mar. 21, 2000, at 8 ("[n]ot a single court has evaluated whether agreements such as these ... are anticompetitive"); Abbott Opp'n, Mar. 20, 2000, at 20.) This assertion is incorrect. American courts have extensive experience with horizontal market allocation agreements and their foreseeable anti-competitive effects.

Without belaboring the point, the undisputed record and the plain text of Abbott's agreements with Geneva and Zenith bespeak the defendants' intent to eliminate domestic competition for sales of terazosin hydrochloride products in the short run and delay the onset of generic competition. Such horizontal agreements to allocate territories remain illegal *per se* under section one of the Sherman Act even if they involve complex disputes involving pharmaceutical companies. *See Maricopa County Med. Soc.*, 457 U.S. at 349, 102 S.Ct. 2466 (rejecting argument that Supreme Court "should not apply the *per se* rule in this case because the judiciary has little antitrust experience in the health care industry"); *Cardizem II*, 105 F.Supp.2d at 705-06 (declaring defendants' horizontal market allocation agreement illegal *per se* ); *Cardizem I*, 105 F.Supp.2d at 676-77 (rejecting "novelty" arguments raised by drug makers HMRI and Andrx to dismiss consolidated Sherman Act challenges). Certainly, the *per se* rule must be "applied infrequently and with caution" to avoid "mislabeling procompetitive activity as *per se* illegal," *Seagood Trading Corp. v. Jerrico*, 924 F.2d 1555, 1567 (11th Cir.1991), but the rule need not "be rejustified for every industry that has not been subject to significant antitrust litigation." *See Maricopa County Med. Soc.*, 457 U.S. at 350-51, 102 S.Ct. 2466. The Sherman Act "establishes one uniform rule applicable to all industries alike." *Socony-Vacuum Oil Co.*, 310 U.S. at 222, 60 S.Ct. 811. Contrary to the defendants' assertions, this case

does not involve "the 'mere attachment of a *per se* label ... to defendants' conduct,' " or an attempt to " 'throw labels ... around loosely.' " (Zenith Opp'n at 13 (citation omitted).) The defendants' confidential and comprehensive allocation of the United States market for the sale of terazosin hydrochloride products should be denounced under the *per se* rule.

**2. Patent Settlements**

Zenith and Abbott claim that the challenged accords are analogous to patent settlement agreements and that the *per se* rule does not apply to such settlements. (Zenith Opp'n at 12; Abbott Opp'n at 26-27 ("antitrust cases considering settlements of patent ... disputes are consistently evaluated under the rule of reason").) Again, the defendants are mistaken. Abbott's agreement with Geneva did not resolve its infringement suit in the Northern District of Illinois, and while Zenith agreed to dismiss its appeal before the Federal Circuit in exchange for three million dollars, this exchange was part of a larger scheme to restrain the domestic sale of generic terazosin hydrochloride products. Furthermore, the Supreme Court has reviewed patent settlements under the *per se* rule. *E.g., United States v. New Wrinkle, Inc.*, 342 U.S. 371, 377, 72 S.Ct. 350, 96 L.Ed. 417 (1952). The *per se* rule applies to the defendants' conduct.

**3. Efforts to Influence Government Action**

Lastly, Abbott seeks the shelter of the *Noerr-Pennington* doctrine, which shields legitimate efforts to influence public officials from potential antitrust liability. (*See* Abbott Opp'n at 27-29) (citing *McGuire Oil Co. v. Mapco*, 958 F.2d 1552, 1560 (11th Cir.1992).) *See generally California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513, 92 S.Ct. 609, 30

L.Ed.2d 642 (1972); *United Mine Workers v. Pennington*, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965); *Eastern R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127, 137-38, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961). The *Noerr-Pennington* doctrine "protect[s] those acts reasonably and normally attendant upon effective litigation," including threats of suit, and demand letters, *Mapco*, 958 F.2d at 1560 (citation omitted), but does not condone contracts bearing a "resemblance to the combinations normally held violative of the Sherman Act, [including] ... market-division agreements." *Noerr Motor Freight*, 365 U.S. at 134-35, 81 S.Ct. at 528; *see Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 507, 108 S.Ct. 1931, 100 L.Ed.2d 497 (1988). Consequently, the challenged agreements are not entitled to refuge under this doctrine.

Abbott's confidential agreements with Geneva and Zenith were not legitimate efforts to influence public officials; rather, they implemented the defendants' scheme to restrain the domestic sale of generic terazosin hydrochloride products without government scrutiny. *Noerr-Pennington* immunity does not apply to restraints adopted by private entities; it extends only when "the alleged restraint of trade [is] the intended consequence of public action." *FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 424-25, 110 S.Ct. 768, 107 L.Ed.2d 851 (1990). Further, clandestine restraints of trade are not "normally attendant upon" patent litigation. Contrary to Abbott's assertion, the Court of Appeals' *Mapco* decision does not "flatly contradict [that] position," or hold that price-fixing stipulations adopted by opposing parties in ongoing litigation are entitled to *Noerr- Pennington* immunity. *See Mapco*, 958 F.2d at 1561-62 (rejecting defendant's narrow argument that plaintiffs' "concerted threats [of suit] and institution of litigation

... violated the Sherman Act"). Abbott's efforts to parlay its patents into agreements with its competitors to limit the domestic sale of generic terazosin hydrochloride drugs is exactly "the type of commercial activity that has traditionally had its validity determined by the antitrust laws." *Allied Tube & Conduit Corp.*, 486 U.S. at 505, 108 S.Ct. 1931.

## CONCLUSION

Both the Geneva Agreement and the Zenith Agreement warrant condemnation as *per se* violations of section one of the Sherman Antitrust Act. This tribunal's extensive review of the undisputed record has validated the presumption that the defendants' horizontal market allocation agreements would tend to inhibit domestic output and price competition without creating efficiencies for American consumers, and the defendants have not adduced sufficient facts to place the illegality of their restraints in genuine dispute. Therefore, for the reasons stated in the foregoing opinion, it is hereby

ORDERED that the Sherman Act Plaintiffs' motion for partial summary judgment [D.E. No. 21, Civ. No. 99-MDL-1317] is GRANTED, and it is

ORDERED that defendant Zenith Goldline Pharmaceuticals, Inc.'s motion for summary judgment [D.E. No. 77, Civ. No. 98-3125; D.E. No. 45, Civ. No. 99- 1938] is DENIED without prejudice to its arguments regarding causation and damages, which may be renewed at the close of Phase II discovery.

DONE and ORDERED in Miami, Florida, this 13th day of December 2000.

S/ Patricia A. Seitz
United States District Judge

**21 U.S.C. § 355. New Drugs**

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. ****

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An Abbreviated application for a new drug shall contain—

* * * *

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

* * * *

(vii) a certification in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under sub-section (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(B)(i) An applicant who makes a certification described in subparagraph (A) (vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or

bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

* * * *

(5)

* * * *

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

* * * *

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration os such day, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonable cooperate in expediting the action, except that—

(I) if before the expiration of such period the court

decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271 (e)(4)(A) of title 35, or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. * * * *

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is

earlier.

## Section 1 of the Sherman Act

**15 U.S.C. § 1. Trusts, etc., in restraint of trade illegal; penalty**

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

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In re: CARDIZEM CD ANTITRUST LITIGATION.

LOUISIANA WHOLESALE DRUG CO., *et al.*

*Plaintiffs-Appellees,*

v.

HOECHST MARION ROUSSEL, INC., and
ANDRX PHARMACEUTICALS, INC.,

*Defendants-Appellants.*

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No. 00-2483

Appeal from the United States District Court
for the Eastern District of Michigan at Detroit.
No. 99-01278 - Nancy G. Edmunds, District Judge.

Argued: April 30, 2002

Decided and Filed: June 13, 2003

Before: SILER and CLAY, Circuit Judges;
OBERDORFER, District Judge.*

* The Honorable Louis F. Oberdorfer, United States District Judge for the District of Columbia, sitting by designation.

COUNSEL

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OPINION

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OBERDORFER, District Judge.

This antitrust case arises out of an agreement entered into by the defendants, Hoescht Marion Roussel, Inc. ("HMR"), the manufacturer of the prescription drug Cardizem CD, and Andrx Pharmaceuticals, Inc. ("Andrx"), then a potential manufacturer of a generic version of that drug. The agreement provided, in essence, that Andrx, in exchange for quarterly payments of $10 million, would refrain from marketing its generic version of Cardizem CD even after it had received FDA approval (the "Agreement"). The plaintiffs are direct and indirect purchasers of Cardizem CD who filed complaints challenging the Agreement as a violation of federal and state antitrust laws. After denying the defendants' motions to dismiss, *see In re Cardizem CD Antitrust Litigation,* 105 F.Supp.2d 618 (E.D.Mich.2000) ("*Dist.Ct.Op. I*") and granting the plaintiffs'

motions for partial summary judgment, *id.*, 105 F.Supp.2d 682 (E.D.Mich.2000) ("*Dist.Ct.Op. II*"), the district court certified two questions for interlocutory appeal:

> (1) ... In determining whether Plaintiffs have properly pled antitrust injury, does the language of the Sixth Circuit's decisions in *Valley Products Co. v. Landmark,* 128 F.3d 398, 404 (6th Cir.1997) and *Hodges v. WSM, Inc.,* 26 F.3d 36, 39 (6th Cir.1994) require dismissal of Plaintiffs' antitrust claims at the pleading stage if Plaintiffs cannot allege facts showing that Defendants' alleged anticompetitive conduct was a "necessary predicate" to their antitrust injury; *i.e.,* that dismissal is required unless Plaintiffs plead facts showing that the alleged antitrust injury could not possibly have occurred absent Defendants' alleged anticompetitive conduct?
>
> (2) ... In determining whether Plaintiffs' motions for partial judgment were properly granted, whether the Defendants' September 24, 1997 Agreement constitutes a restraint of trade that is illegal *per se* under section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and under the corresponding state antitrust laws at issue in this litigation.

JA 607. Our answers, explained more fully herein, are as follows:

*Answer to First Certified Question:* As framed, the certified

question is not susceptible to a yes or no answer because it incorporates a definition of "necessary predicate" that we reject. *Hodges* and *Valley Products* stand for the proposition that in order to survive a motion to dismiss for failure to allege antitrust injury, a plaintiff must allege that the antitrust violation is *either* the "necessary predicate" for its injury *or* the only means by which the defendant could have caused its injury. Under the "necessary predicate" option, dismissal is warranted only where it is apparent from the allegations in the complaints that the plaintiffs' injury would have occurred even if there had been no antitrust violation. Here, Andrx could have made a unilateral and legal decision to delay its market entry, but the plaintiffs have alleged it would not have done so but for the Agreement and HMR's payment to it of $40 million per year. The plaintiffs' allegations satisfy the "necessary predicate" test. The defendants' claim that Andrx's decision to stay off the market was motivated not by the $40 million per year it was being paid by HMR, but by its fear of damages in the pending patent infringement litigation, merely raises a disputed issue of fact that cannot be resolved on a motion to dismiss. Accordingly, the district court properly denied the defendants' motions to dismiss for failure to allege antitrust injury.

*Answer to Second Certified Question:* Yes. The Agreement whereby HMR paid Andrx $40 million per year not to enter the United States market for Cardizem CD and its generic equivalents is a horizontal market allocation agreement and, as such, is *per se* illegal under the Sherman Act and under the corresponding state antitrust laws. Accordingly, the district court properly granted summary judgment for the plaintiffs on the issue of whether the Agreement was *per se* illegal.

## I. BACKGROUND

As the district court has set forth a complete outline of the relevant statutory framework, *see Dist. Ct. Op. I*, at 627-29; *Dist. Ct. Op. II*, at 685-86, facts, *see Dist. Ct. Op. I*, at 629-32; *Dist. Ct. Op. II*, at 686-89, and procedural history, *see Dist. Ct. Op. I*, at 632-33; *Dist. Ct. Op. II*, at 689-90, we repeat here only what is necessary to our analysis of the issues on appeal.

### A. Statutory Framework

In 1984, Congress enacted the Hatch-Waxman Amendments, *see* Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399. Those amendments permit a potential generic [1] manufacturer of a patented pioneer drug to file an abbreviated application for approval with the Food and Drug Administration ("FDA") (known as an Abbreviated New Drug Application ("ANDA")). *See* 21 U.S.C. § 355(j)(1). Instead of submitting new safety and efficacy studies, an ANDA may rely on the FDA's prior determination, made in the course of approving an earlier "pioneer" drug, that the active ingredients of the proposed new drug are safe and effective. *Id.* § 355(j)(2)(A). Every ANDA must include a "certification that, in the opinion of the applicant and to the best of his knowledge, the proposed generic drug does not infringe any patent listed with the FDA as covering the pioneer drug." *Id.* §

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[1] A "generic" drug contains the same active ingredients but not necessarily the same inactive ingredients as a "pioneer" drug sold under a brand name. *United States v. Generix Drug Corp.*, 460 U.S. 453, 454-55, 103 S.Ct. 1298, 75 L.Ed.2d 198 (1983).

355(j)(2)(A)(vii). That certification can take several forms. Relevant here is the so-called "paragraph IV certification" whereby the applicant certifies that any such patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(j)(2)(A)(vii)(IV). An applicant filing a paragraph IV certification must give notice to the patent-holder, *id.* § 355(j)(2)(B); the patent-holder then has forty-five days to file a patent infringement action against the applicant. *Id.* § 355(j)(5)(B)(iii). If the patent-holder files suit, a thirty-month stay goes into effect, meaning that unless before that time the court hearing the patent infringement case finds that the patent is invalid or not infringed, the FDA cannot approve the generic drug before the expiration of that thirty-month period. *Id.* § 355(j)(5)(B)(iii)(I). In order to encourage generic entry, and to compensate for the thirty-month protective period accorded the patent holder, the first generic manufacturer to submit an ANDA with a paragraph IV certification receives a 180-day period of exclusive marketing rights, during which time the FDA will not approve subsequent ANDA applications. *Id.* § 355(j)(5)(B)(iv). The 180-day period of exclusivity begins either (1) when the first ANDA applicant begins commercial marketing of its generic drug (the marketing trigger) or (2) when there is a court decision ruling that the patent is invalid or not infringed (the court decision trigger), whichever is earlier. *Id.*

**B. Facts**

Unless otherwise noted, the following facts are undisputed. HMR manufactures and markets Cardizem CD, a brand-name prescription drug which is used for the treatment of angina and hypertension and for the prevention of heart

attacks and strokes. The active ingredient in Cardizem CD is diltiazem hydrochloride, which is delivered to the user through a controlled-release system that requires only one dose per day. HMR's patent for diltiazem hydrochloride expired in November 1992.

On September 22, 1995, Andrx filed an ANDA with the FDA seeking approval to manufacture and sell a generic form of Cardizem CD. On December 30, 1995, Andrx filed a paragraph IV certification stating that its generic product did not infringe any of the patents listed with the FDA as covering Cardizem CD. Andrx was the first potential generic manufacturer of Cardizem CD to file an ANDA with a paragraph IV certification, entitling it to the 180-day exclusivity period once it received FDA approval.

In November 1995, the United States patent office issued Carderm Capital, L.P. ("Carderm") U.S. Patent No. 5,470,584 ("'584 patent"), for Cardizem CD's "dissolution profile," which Carderm licensed to HMR. JA 1796-1810. The dissolution profile claimed by the '584 patent was for 0-45% of the total diltiazem to be released within 18 hours ("45%-18 patent").[2]

In January 1996, HMR and Carderm filed a patent infringement suit against Andrx in the United States District Court for the Southern District of Florida, asserting that the generic version of Cardizem CD that Andrx proposed would infringe the '584 patent. *See* JA 1240-1257 (Complaint, *Hoescht Marion Roussel, Inc. v. Andrx Pharmaceuticals, Inc.*,

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[2] Two other patents for the dissolution profile of Cardizem CD had previously been issued, one in February 1994 and one in August 1995. Neither is relevant to the present litigation.

No. 96-06121 (S.D. Fla. filed Jan. 31, 1996)). The complaint sought neither damages nor a preliminary injunction. *Id.* However, filing that complaint automatically triggered the thirty-month waiting period during which the FDA could not approve Andrx's ANDA and Andrx could not market its generic product. In February 1996, Andrx brought antitrust and unfair competition counterclaims against HMR. JA 1717-47. In April 1996, Andrx amended its ANDA to specify that the dissolution profile for its generic product was not less than 55% of total diltiazem released within 18 hours ("55%-18 generic"). HMR nonetheless continued to pursue its patent infringement litigation against Andrx in defense of its 45%- 18 patent. On June 2, 1997, Andrx represented to the patent court that it intended to market its generic product as soon as it received FDA approval. JA 1758.

On September 15, 1997, the FDA tentatively approved Andrx's ANDA, indicating that it would be finally approved as soon as it was eligible, either upon expiration of the thirty-month waiting period in early July 1998, or earlier if the court in the patent infringement action ruled that the '584 patent was not infringed.

Nine days later, on September 24, 1997, HMR and Andrx entered into the Agreement. JA 1363-73. It provided that Andrx would not market a bioequivalent or generic version of Cardizem CD in the United States until the earliest of: (1) Andrx obtaining a favorable, final and unappealable determination in the patent infringement case; (2) HMR and Andrx entering into a license agreement; *or* (3) HMR entering into a license agreement with a third party. Andrx also agreed to dismiss its antitrust and unfair competition counterclaims, to diligently prosecute its ANDA, and to not "relinquish or

otherwise compromise any right accruing thereunder or pertaining thereto," including its 180-day period of exclusivity. In exchange, HMR agreed to make interim payments to Andrx in the amount of $40 million per year, payable quarterly, beginning on the date Andrx received final FDA approval.[3] HMR further agreed to pay Andrx $100 million per year,[4] less whatever interim payments had been made, once: (1) there was a final and unappealable determination that the patent was not infringed; (2) HMR dismissed the patent infringement case; or (3) there was a final and unappealable determination that did not determine the issues of the patent's validity, enforcement, or infringement, and HMR failed to refile its patent infringement action.[5] HMR also agreed that it would not seek preliminary injunctive relief in the ongoing patent infringement litigation. [6]

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[3] The payments were scheduled to end on the earliest of: (1) a final and unappealable order or judgment in the patent infringement case; (2) if HMR notified Andrx that it intended to enter into a license agreement with a third party, the earlier of: (a) the expiration date of the required notice period or (b) the date Andrx effected its first commercial sale of the Andrx product; or (3) if Andrx exercised its option to acquire a license from HMR, the date the license agreement became effective.

[4] HMR and Andrx stipulated that, for the purposes of the Agreement, Andrx would have realized $100 million per year in profits from the sale of its generic product after receiving FDA approval.

[5] HMR had to notify Andrx within thirty days of such a determination that it continued to believe that Andrx's generic version of the drug infringed its patent and that it intended to refile its patent infringement action.

[6] HMR also agreed that it would give Andrx copies of changes it proposed to the FDA regarding Cardizem CD's package insert and immediate container label, that it would notify Andrx of any labeling changes pending before or approved by the FDA, and that it would grant Andrx an

On July 8, 1998, the statutory thirty-month waiting period expired. On July 9, 1998, the FDA issued its final approval of Andrx's ANDA. Pursuant to the Agreement, HMR began making quarterly payments of $10 million to Andrx, and Andrx did not bring its generic product to market.

On September 11, 1998, Andrx, in a supplement to its previously filed ANDA, sought approval for a reformulated generic version of Cardizem CD. Andrx informed HMR that it had reformulated its product; it also urged HMR to reconsider its infringement claims. On February 3, 1999, Andrx certified to HMR that its reformulated product did not infringe the '584 patent.

On June 9, 1999, the FDA approved Andrx's reformulated product. That same day, HMR and Andrx entered into a stipulation settling the patent infringement case and terminating the Agreement. At the time of settlement, HMR paid Andrx a final sum of $50.7 million, bringing its total payments to $89.83 million. On June 23, 1999, Andrx began to market its product under the trademark Cartia XT, and its 180-day period of marketing exclusivity began to run. Since its release, Cartia XT has sold for a much lower price than Cardizem CD and has captured a substantial portion of the market.

**C. Procedural History**

The first complaint challenging the legality of the Agreement was filed in August 1998, shortly after the FDA

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irrevocable option to acquire a nonexclusive license to all intellectual property HMR owned or controlled that Andrx might need to market its product in the United States.

issued its final approval for Andrx's generic version of Cardizem CD. That complaint, and the other complaints that were subsequently filed, have been consolidated by the Judicial Panel on Multidistrict Litigation, pursuant to 28 U.S.C. § 1407, for coordinated or consolidated pretrial proceedings in the Eastern District of Michigan. [7] JA 56-58.

For all of the plaintiffs, the foundation for their claims is the allegation that but for the Agreement, specifically the payment of $40 million per year, Andrx would have brought its generic product to market once it received FDA approval and at a lower price than the patented Cardizem CD sold by HMR. They further allege that the Agreement protected HMR from competition from both Andrx and other potential generic competitors because Andrx's delayed market entry postponed the start of its 180-day exclusivity period, which it had agreed not to relinquish or transfer. The Sherman Act Class Plaintiffs and the Individual Sherman Act Plaintiffs bring claims under the federal antitrust laws, specifically section 1 of the Sherman Act, 15 U.S.C. § 1; they seek treble damages under section 4

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[7]As described by the district court, the plaintiffs fall into three groups: (1) the "State Law Plaintiffs," indirect purchasers, and class representatives, from various states whose complaints, initially filed in state court and then removed to federal district court by defendants, allege violations of state antitrust and consumer protection statutes, JA 908-1011; (2) the "Sherman Act Class Plaintiffs," direct purchasers, and class representatives, whose complaint, filed in federal district court, alleges a violation of federal antitrust law, JA 139-159; and (3) the "Individual Sherman Act Plaintiffs," two groups of purchasers, not representatives of any class, whose complaints, filed in federal district court, allege violations of federal antitrust law, JA 860-881 (filed by The Kroger Co., Albertson's, Inc., The Stop and Shop Supermarket Co., and Eckerd Corp.); JA 887-896 (filed by CVS Meridian, Inc. and Rite Aid Corp.). *See Dist. Ct. Op. I*, at 625-27. Each group has filed a brief on appeal.

of the Clayton Act, 15 U.S.C. § 4. The State Law Class Plaintiffs bring claims under various state antitrust laws.[8]

The defendants, HMR and Andrx, filed various motions to dismiss, all of which were denied. *See Dist. Ct. Op. I*, at 624. Of relevance to the present appeal, the defendants argued that all of the plaintiffs had failed to allege and could not allege an "antitrust injury" cognizable under section 1 of the Sherman Act or under the respective state antitrust statutes. *Id.* at 645. The district court concluded that the plaintiffs had adequately alleged "antitrust injury." *Id.* at 645-58. In reaching its conclusion, the district court first considered whether the plaintiffs' allegations satisfied the test articulated by the Supreme Court in *Brunswick Corp. v. Pueblo Bowl- O-Mat, Inc.*, 429 U.S. 477, 489, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977). In *Brunswick,* the Supreme Court defined "antitrust injury" as "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." 429 U.S. at 489, 97 S.Ct. 690. The district court explained its conclusion that the plaintiffs satisfied this test as follows:

> As to the first prong of the antitrust injury test, the Supreme Court has observed that "[t]he Sherman Act was enacted to assure our customers the benefits of price competition, and our prior cases have emphasized the central interest in protecting the economic freedom of

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[8] Of the State Law Plaintiffs, the plaintiffs from seven states (California, Michigan, Minnesota, New York, North Carolina, Tennessee, and Wisconsin) and the District of Columbia claim violations of state antitrust law. *Dist. Ct. Op. I,* at 625 n. 3.

> participants in the relevant market." *Associated General,* 459 U.S. at 538, 103 S.Ct. 897. Plaintiffs are customers, not competitors of Defendants, and the injury claimed consists of higher prices paid for drugs as a result of the contractually mandated absence of competition between HMRI and Andrx. As to the second, or causal connection prong of the antitrust injury test, Plaintiffs have alleged that the HMRI/Andrx Agreement decreased generic competition, and that the decreased competition bargained for in the HMRI/Andrx Agreement caused their injuries. Thus, Plaintiffs' injuries coincide precisely with the rationale for finding a violation of the antitrust laws in the first place. Since the very purpose of antitrust law is to ensure that the benefits of competition flow to purchasers of goods affected by the violation, "buyers have usually been preferred plaintiffs in private antitrust litigation," and a purchaser's standing "to recover for an overcharge paid directly to an illegal cartel or monopoly is seldom doubted." 2 P. Areeda & H. Hovemkamp, supra, ¶ 370[,] at 253. Plaintiffs have sufficiently pled facts that show they satisfy the "antitrust injury" test set forth in *Brunswick.*

*Dist. Ct. Op. I,* at 650-51. The district court then considered whether the Sixth Circuit's decisions in *Axis, S.p.A. v. Micafil,* 870 F.2d 1105 (6th Cir.1989), *Hodges v. WSM, Inc.,* 26 F.3d 36 (6th Cir.1994), and *Valley Products Co. v. Landmark,* 128 F.3d 398 (6th Cir.1997) required a different

conclusion, *Dist. Ct. Op. I*, at 651-57, particularly the statement in *Hodges* that "because plaintiffs did not allege, nor could they that the illegal antitrust conduct was a necessary predicate to their injury *or* that defendants could exclude plaintiffs only by engaging in the antitrust violation, it was appropriate to dismiss the case." 26 F.3d at 39 (emphasis added). After closely examining the facts and holdings of those cases, it rejected the defendants' contention that the Sixth Circuit's "necessary predicate" test meant that an antitrust complaint should be dismissed "simply because the defendant can conjure up a set of facts, contradicting those alleged in the plaintiff's complaint, but supporting an alternative possible cause for Plaintiffs' injuries that would not offend the antitrust laws." *Dist. Ct. Op. I*, at 651. It explained further:

> While the Sixth Circuit language found in the last paragraph of *Hodges* and repeated in *Valley Products* appears to broadly apply to the facts presented here, careful examination of these decisions reveals otherwise. The quoted language goes well beyond the antitrust injury test announced in *Brunswick*, goes well beyond what the Sixth Circuit actually did in each of these cases, goes further than the underlying facts allow, and is mutually inconsistent with the material cause standard that is to be applied in antitrust cases.

*Id.* at 652. Accordingly, the district court denied the defendants' motions to dismiss for failure to allege antitrust injury.

The plaintiffs then moved for partial summary judgment on the issue of whether the Agreement was a *per se* illegal

restraint of trade. The district court concluded that the Agreement, specifically the fact that HMR paid Andrx $10 million per quarter not to enter the market with its generic version of Cardizem CD, was a naked, horizontal restraint of trade and, as such, *per se* illegal. *Dist. Ct. Op. II*, at 705-06.

Pursuant to 28 U.S.C. § 1292(b), the district court certified for interlocutory appeal the two questions quoted above. [9]

## II. DISCUSSION

As we believe that our answer to the second question sheds light on our consideration of the first, we address first whether the Agreement was a *per se* illegal restraint of trade before considering whether the plaintiffs adequately alleged antitrust injury.

### A. *Per Se* Illegal Restraint of Trade

We review *de novo* the district court's ruling on summary judgment that the Agreement was a *per se* illegal restraint of trade. *Holloway v. Brush,* 220 F.3d 767, 772 (6th Cir.2000). Summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving party is

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[9] Since oral argument before this Court, the defendants have reached a settlement with the Sherman Act Class Plaintiffs. A settlement with the State Law Plaintiffs and the State Attorneys' General is subject for a final approval hearing before the District Court in October 2003. The Sherman Act Individual Plaintiffs have settled with HMR (now Aventis Pharmaceuticals), but have not settled with Andrx. The defendants have represented to the Court that these settlements have not mooted the certified issues presented by this appeal. *See* Letter to U.S. Court of Appeals for the Sixth Circuit, filed Feb. 20, 2003.

entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c).

**1. Relevant Antitrust Law**

Section 1 of the Sherman Act[10] provides that "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal...." 15 U.S.C. § 1. Read "literally," section 1 "prohibits *every* agreement in restraint of trade." *Arizona v. Maricopa Cty. Medical Soc.*, 457 U.S. 332, 342, 102 S.Ct. 2466, 73 L.Ed.2d 48 (1982). However, the Supreme Court has long recognized that Congress intended to outlaw only "unreasonable" restraints. *State Oil Co. v. Khan,* 522 U.S. 3, 10, 118 S.Ct. 275, 139 L.Ed.2d 199 (1997); *Maricopa Cty.*, 457 U.S. at 342-43, 102 S.Ct. 2466 (citing *United States v. Joint Traffic Ass'n,* 171 U.S. 505, 19 S.Ct. 25, 43 L.Ed. 259 (1898)). Most restraints are evaluated using a "rule of reason." *State Oil,* 522 U.S. at 10, 118 S.Ct. 275. Under this approach, the "finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *Id.* (citing *Maricopa Cty.*, 457 U.S. at 343 & n. 13, 102 S.Ct. 2466).

Other restraints, however, "are deemed unlawful *per se*" because they "have such predictable and pernicious

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[10] It is undisputed that the state antitrust statutes at issue either follow federal Sherman Act precedent or find federal case law persuasive. *See* State Law Pls. Br. at 41-44.

anticompetitive effect, and such limited potential for procompetitive benefit." *Id.* (citing *Northern Pacific Ry. Co. v. United States,* 356 U.S. 1, 5, 78 S.Ct. 514, 2 L.Ed.2d 545 (1958)). "*Per se* treatment is appropriate '[o]nce experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it.' " *Id.* (quoting *Maricopa Cty.,* 457 U.S. at 344, 102 S.Ct. 2466); *see also Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.,* 441 U.S. 1, 19-20, 99 S.Ct. 1551, 60 L.Ed.2d 1 (1979) (a *per se* rule is applied when "the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output."). The *per se* approach thus applies a "conclusive presumption" of illegality to certain types of agreements, *Maricopa Cty.,* 457 U.S. at 344, 102 S.Ct. 2466; where it applies, no consideration is given to the intent behind the restraint, to any claimed pro-competitive justifications, or to the restraint's actual effect on competition.[11] *National College Athletic Ass'n ("NCAA") v. Board of Regents,* 468 U.S. 85, 100, 104 S.Ct. 2948, 82 L.Ed.2d 70 (1984). As explained by the Supreme Court, "[t]he probability that anticompetitive consequences will result from a practice and the severity of those consequences must be balanced against its procompetitive

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[11] The risk that the application of a *per se* rule will lead to the condemnation of an agreement that a rule of reason analysis would permit has been recognized and tolerated as a necessary cost of this approach. *See, e.g., Maricopa Cty.,* 457 U.S. at 344, 102 S.Ct. 2466 ("As in every rule of general application, the match between the presumed and the actual is imperfect. For the sake of business certainty and litigation efficiency, we have tolerated the invalidation of some agreements that a full-blown inquiry might have proved to be reasonable."); *United States v. Topco Associates, Inc.,* 405 U.S. 596, 609, 92 S.Ct. 1126, 31 L.Ed.2d 515 (1972) ("Whether or not we would decide this case the same way under the rule of reason used by the District Court is irrelevant to the issue before us.").

consequences. Cases that do not fit the generalization may arise, but a *per se* rule reflects the judgment that such cases are not sufficiently common or important to justify the time and expense necessary to identify them." *Continental T.V., Inc. v. GTE Sylvania Inc.,* 433 U.S. 36, 50 n. 6, 97 S.Ct. 2549, 53 L.Ed.2d 568 (1977).

The Supreme Court has identified certain types of restraints as subject to the *per se* rule. The classic examples are naked, horizontal restraints pertaining to prices or territories. *See, e.g., NCAA,* 468 U.S. at 100, 104 S.Ct. 2948 ("Horizontal price fixing and output limitation are ordinarily condemned as a matter of law under an 'illegal *per se*' approach because the probability that these practices are anticompetitive is so high."); *Copperweld Corp. v. Independence Tube Corp.,* 467 U.S. 752, 768, 104 S.Ct. 2731, 81 L.Ed.2d 628 (1984) ("Certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal *per se* without inquiry into the harm it has actually caused."); *United States v. Topco Assocs.,* 405 U.S. 596, 608, 92 S.Ct. 1126, 31 L.Ed.2d 515 (1972) ("One of the classic examples of a *per se* violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition. Such concerted action is usually termed a 'horizontal' restraint, in contradistinction to combinations of persons at different levels of the market structure, *e.g.,* manufacturers and distributors, which are termed 'vertical' restraints. This Court has reiterated time and time again that horizontal territorial limitations ... are naked restraints of trade with no purpose except stifling of competition. Such limitations are *per se* violations of the Sherman Act." (internal citations omitted)); *Northern Pacific Ry.,* 356 U.S. at 5, 78 S.Ct. 514 ("Among the practices which

the courts have heretofore deemed to be unlawful in and of themselves are price fixing, division of markets, group boycotts, and tying arrangements." (internal citations omitted)).

**2. Application**

In answering the question whether the Agreement here was *per se* illegal, the following facts are undisputed and dispositive. The Agreement guaranteed to HMR that its only potential competitor at that time, Andrx, would, for the price of $10 million per quarter, refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval, protecting HMR's exclusive access to the market for Cardizem CD throughout the United States until the occurrence of one of the end dates contemplated by the Agreement. (In fact, Andrx and HMR terminated the Agreement and the payments in June 1999, before any of the specified end dates occurred.) In the interim, however, from July 1998 through June 1999, Andrx kept its generic product off the market and HMR paid Andrx $89.83 million. By delaying Andrx's entry into the market, the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish or transfer. [12] There is simply no

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[12] As the district court for the Eastern District of New York recently observed, in distinguishing the district court's opinion in the present case (*Cardizem II*),

> By agreeing both not to end the underlying patent dispute and not to market a generic drug product in the relevant domestic market, Andrx ... effectively precluded or seriously delayed both the [patent] court decision and the commercial marketing trigger of the 180-day exclusivity period. As a result, any future [generic] filers

escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.

None of the defendants' attempts to avoid *per se* treatment is persuasive. As explained in greater detail in the district court's opinion, *see Dist. Ct. Op. II*, at 700-705, the Agreement cannot be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation. As the plaintiffs point out, it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness [13] in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market. Individual Sherman Act Plaintiffs Br. at 26- 30. Nor does the fact that this is a "novel" area of law preclude *per se* treatment, *see Maricopa*

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were delayed in coming to market....

*In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F.Supp.2d 188, 242, MDL No. 1383, 2003 WL 21146562, at *46 (E.D.N.Y. May 20, 2003); *see also In re Tamoxifen Citrate Antitrust Litigation*, --- F.Supp.2d ----, ----, MDL No. 1408, 2003 WL 21196817, at *9 (E.D.N.Y. May 13, 2003).

[13] As the court in *In re Ciprofloxacin* observed,

[w]hen the Cardizem [district] court condemned the HMR/Andrx Agreement, it emphasized that the agreement [there] restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation,.... Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem. 261 F.Supp.2d at 242, 2003 WL 21146562, at *46.

*Cty.*, 457 U.S. at 349, 102 S.Ct. 2466. To the contrary, the Supreme Court has held that " '[w]hatever may be its peculiar problems and characteristics, the Sherman Act, so far as price-fixing agreements are concerned, establishes one uniform rule applicable to all industries alike.' " *Id.* at 349, 102 S.Ct. 2466 (quoting *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 222, 60 S.Ct. 811, 84 L.Ed. 1129 (1940)). We see no reason not to apply that rule here, especially when the record does not support the defendants' claim that the district court made "errors" in its analysis.[14] Finally, the defendants' claims that the Agreement lacked anticompetitive effects and had procompetitive benefits are simply irrelevant. *See, e.g., Maricopa Cty.*, 457 U.S. at 351, 102 S.Ct. 2466. To reiterate, the virtue/vice of the *per se* rule is that it allows courts to presume that certain behaviors as a class are anticompetitive without expending judicial resources to evaluate the actual anticompetitive effects or procompetitive justifications in a

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[14]For example, the defendants charge that the district court erred in concluding that in the absence of the Agreement, Andrx *would* have marketed its generic product before the end of the patent litigation (once it had received FDA approval). However, the district court never held that Andrx *would* have launched the original formulation of its generic while the patent suit was pending, only that it *could* have. The defendants also contend that the district court erred in assuming that Andrx could have marketed its *reformulated* generic, which only received FDA approval in June 1999, before it did, but the district court made no such assumption. Finally, the defendants argue that the district court erred in reaching the conclusion that Andrx and HMRI were horizontal competitors. They maintain that it would be inconsistent with Hatch-Waxman scheme to allow a court to treat a generic manufacturer who is seeking FDA approval and has been charged with patent infringement and the patent holder as horizontal competitors. Hatch-Waxman notwithstanding, the defendants are potential rivals in the market for Cardizem CD; an agreement between them is thus an agreement between horizontal competitors

particular case. As the Supreme Court explained in *Maricopa County:*

> The respondents' principal argument is that the *per se* rule is inapplicable because their agreements are alleged to have procompetitive justifications. The argument indicates a misunderstanding of the *per se* concept. The anticompetitive potential inherent in all price-fixing agreements justifies their facial invalidation even if procompetitive justifications are offered for some. Those claims of enhanced competition are so unlikely to prove significant in any particular case that we adhere to the rule of law that is justified in its general application.

457 U.S. at 351, 102 S.Ct. 2466. Thus, the law is clear that once it is decided that a restraint is subject to *per se* analysis, the claimed lack of any actual anticompetitive effects or presence of procompetitive effects is irrelevant. Of course, our holding here does not resolve the issues of causation and damages, both of which will have to be proved before the plaintiffs can succeed on their claim for treble damages under the Clayton Act.

**B. Antitrust Injury**

We now consider whether the district court properly denied the defendants' motion to dismiss the complaint for failure to allege an "antitrust injury."[15] A district court's denial

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[15] Our conclusion that the Agreement was a *per se* illegal restraint of trade

of a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) is subject to *de novo* review. *Ziegler v. IBP Hog Market, Inc.*, 249 F.3d 509, 511-12 (6th Cir.2001). In deciding a motion to dismiss, we, like the district court, "must construe the complaint in the light most favorable to the plaintiff, accept all of the complaint's factual allegations as true, and determine whether the plaintiff undoubtedly can prove no set of facts in support of his claim that would entitle him to relief." *Id.* at 512. "When an allegation is capable of more than one inference, it must be construed in the plaintiff's favor." *Helwig v. Vencor, Inc.*, 251 F.3d 540, 553 (6th Cir.2001) (internal citations omitted), *cert. dismissed*, 536 U.S. 935, 122 S.Ct. 2616, 153 L.Ed.2d 800 (2002).

**1. Relevant Antitrust Law**

A private antitrust plaintiff, in addition to having to show injury-in-fact and proximate cause, must allege, and eventually prove, "antitrust injury." *Brunswick*, 429 U.S. at 489, 97 S.Ct. 690. "Antitrust injury" is (1) "injury of the type the antitrust laws were intended to prevent" and (2) injury "that flows from that which makes defendants' acts unlawful." *Id.* As explained by the Supreme Court in *Brunswick*, the antitrust injury doctrine is designed to ensure that "the injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *Id.* The

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does not obviate the need to decide whether the plaintiffs adequately alleged antitrust injury. *See Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 341-42, 110 S.Ct. 1884, 109 L.Ed.2d 333 (1990) ("The *per se* rule is a method of determining whether 1 of the Sherman Act has been violated, but it does not indicate whether a private plaintiff has suffered antitrust injury and thus whether he may recover damages under § 4 of the Clayton Act.").

Supreme Court has further explained the requirement as "ensur[ing] that the harm claimed by the plaintiff corresponds to the rationale for finding a violation of the antitrust laws in the first place," and, more specifically, it "ensures that a plaintiff can recover only if the loss stems from a competition-*reducing* aspect or effect of the defendant's behavior." *Atlantic Richfield Co. v. USA Petroleum Co.* 495 U.S. 328, 342-343, 110 S.Ct. 1884, 109 L.Ed.2d 333 (1990).

**2. Plaintiffs' Allegations**

In the present case, the plaintiffs' critical allegations include the following: (1) Andrx had developed and was ready to market a generic version of Cardizem CD; (2) Andrx had certified to the FDA that its generic product did not infringe any of the patents associated with Cardizem CD; (3) the patent infringement litigation was a "sham"[16]; (4) prior to entering into the Agreement, Andrx had represented to the federal district court presiding over the patent infringement litigation

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[16] The State Law Plaintiffs allege that the '584 patent "represented no substantive change or improvement to Cardizem CD but rather was prosecuted and listed solely to give HMR a basis for initiating sham patent infringement litigation to delay and exclude Andrx's generic Cardizem CD from the Cardizem CD market for at least 30 months." JA 948, ¶ 101. They further allege that Andrx's specified dissolution profile, submitted to the FDA after the patent infringement litigation was filed, was "clearly distinct" from the '584 patent, JA 949, ¶ 103, and that HMR continued its pursuit of the patent infringement litigation "despite the absence of any reasonable belief that their claim would be held to be valid upon adjudication," *id.* ¶ 104. Finally, they allege that HMR's "goal and intention in pursuing [the patent infringement litigation] was solely to indefinitely delay and prevent the entry of Andrx's product into the marketplace and invoke the automatic 30-month administrative delay in the FDA approval process." *Id.; see also* JA 154, ¶ 53 (amended complaint of Sherman Act Class Plaintiffs alleging that "patent litigation" was "sham[ ]").

that it intended to market and sell its generic version of Cardizem CD as soon as it received final FDA approval; (5) the Agreement entered into by Andrx and HMR provided, among other things, that once the FDA approved Andrx's ANDA, HMR would commence making quarterly payments of $10 million in exchange for Andrx not bringing its generic product to market; (6) Andrx did not enter the market upon receiving FDA approval on July 9, 1998; (7) pursuant to the Agreement, HMR ultimately paid Andrx $89.83 million; (8) "but for" the Agreement and the payment, Andrx would have begun to market its generic version of Cardizem CD on or shortly after July 9, 1998; (9) the Agreement effectively eliminated generic competition in the market for Cardizem CD from July 1998 through July 1999, when the Agreement was terminated; and (10) due to the lack of a competitive market, the plaintiffs were deprived of the option of purchasing a generic lower-priced drug and paid more than they otherwise would have for Cardizem CD. JA 908-1011 (State Law Pls. Compl.); JA 139-159 (Sherman Act Class Pls. Compl.); JA 848-859, 860-881, 887-896 (Individual Sherman Act Pls. Compls.); *see also Dist. Ct. Op. I*, at 647.

**3. Application of *Brunswick***

The plaintiffs' allegations fall easily within the two critical *Brunswick* categories. It is clear, and not disputed on appeal, that the plaintiffs have alleged the "type of injury" the antitrust laws were meant to prevent. The plaintiffs are consumers of the patented drug Cardizem CD, who allege that they were deprived of a less expensive generic product, forcing them to purchase the higher-priced brand name product, because of a *per se* illegal horizontal market restraint. Preventing that kind of injury was undoubtedly a *raison d'etre* of the Sherman Act

when it was enacted in 1890. *See Associated Gen. Contractors v. California State Council,* 459 U.S. 519, 538, 103 S.Ct. 897, 74 L.Ed.2d 723 (1983).

There remains the issue of whether the alleged injury "flows" from that "which makes defendants' acts unlawful," i.e., its anticompetitive effects. The facts of *Brunswick* shed light on the meaning and purpose of this requirement. In *Brunswick,* a bowling alley owner claimed that another competitor's takeover of two failing bowling alleys was an illegal merger. The plaintiff alleged that it was injured by the merger because if the other bowling alleys had simply gone out of business, it would have increased its sales in the bowling alley market. What would have made the acquisition unlawful for antitrust purposes, however, was the risk that increased concentration in the bowling alley market would reduce future competition and cause prices to rise. The plaintiff's injury, on the other hand, flowed from the more immediate competition-enhancing effects of the merger; not its future potential to reduce competition. Accordingly, there was no antitrust injury because the plaintiff's injury did not "flow" from the anticompetitive effects of the alleged antitrust violation.

In the present case, the facts are much more straightforward. As explained above, the alleged antitrust violation, HMR's agreement to pay Andrx $40 million per year not to bring its generic product to market and compete with Cardizem CD, is a naked, horizontal restraint of trade that is *per se* illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers. Unlike in *Brunswick,* here there is no question that the alleged injury--paying higher prices for a product due to a lack of competition

in the market-- is the type of injury that can, and the plaintiffs have alleged did, flow from the anticompetitive effects of the Agreement (a horizontal market allocation agreement). Under these circumstances, dismissal would be appropriate only if the plaintiffs' allegations, taken as true and construed in their favor, somehow precluded the possibility that their injury flowed from the anticompetitive effects of the Agreement and payment. No such conclusion can be reached in this case. To the contrary, the complaint clearly alleges that but for the Agreement, specifically the payment of $40 million per year, the plaintiffs would not have suffered their injury; there is nothing in the complaint that belies this allegation or justifies this Court not accepting it as true. The defendants' argument to the contrary, that Andrx would not have entered the market even if there had been no Agreement and payment because of its fear of damages in the patent infringement litigation, creates a disputed issue of fact, not appropriately resolved on a motion to dismiss. Indeed, a trier of fact may well find that the $89 million payment renders incredible the defendants' claim that Andrx would have refrained from marketing simply because of its fear of infringement damages.

**4. "Necessary Predicate" Test**

We turn now to the defendants' contention, and the reason for this certified appeal, that the Sixth Circuit's "necessary predicate" test requires more than *Brunswick* and leads to a different conclusion.[17] The defendants' argument arises out of

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[17] It is noteworthy that the district court has responsibility for these cases by assignment of the Judicial Panel on Multidistrict Litigation, and we address this certified question in aid of the district court. This consolidated proceeding includes cases that were originally filed in various state and

a statement made in this Court's decision in *Hodges*. In that case, after having decided to affirm the district court's dismissal for failure to allege antitrust injury, the Court stated: "[b]ecause plaintiffs did not allege, nor could they, that the illegal antitrust conduct was a necessary predicate to their injury *or* that defendants could exclude plaintiffs only by engaging in the antitrust violation, it was appropriate to dismiss the case pursuant to Federal Rule of Civil Procedure 12(b)(6)." *Hodges*, 26 F.3d at 39 (emphasis added).

The defendants contend that this statement means that in

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federal courts, raising state and federal antitrust claims. The state cases were first removed to federal district court and then transferred to the Eastern District of Michigan. In considering the issue of antitrust injury, the district court applied the same analysis, including the application of Sixth Circuit precedent, to all of the antitrust claims. *Id.* at 645-58. As no party has taken issue with this approach, either before the district court or on appeal, we have followed the same path. We note, however, that although it is clear and undisputed that the state antitrust laws at issue all "either follow federal Sherman Act precedent or find federal case law persuasive," *Dist. Ct. Op. II*, at 692 & n. 6 (citing state cases); *see also* State Law Pls. Br. at 41-15, and that in a federal multidistrict litigation there is a preference for applying the law of the transferee district, *see In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig.*, 97 F.3d 1050 (8th Cir.1996); *Menowitz v. Brown*, 991 F.2d 36 (2d Cir.1993), it is not clear that precedent "unique" to a particular circuit and arguably divergent from the predominant interpretation of a federal law, such as the Sixth Circuit's "necessary predicate" gloss on the antitrust injury doctrine, should be applied to state antitrust laws or federal antitrust claims that originated in other circuits, *see In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171 (D.C.Cir.1987), *aff'd*, 490 U.S. 122, 109 S.Ct. 1676, 104 L.Ed.2d 113 (1989) (law of transferor forum on federal question merits close consideration, but does not have *stare decisis* effect). As we agree with the district court that the plaintiffs have alleged antitrust injury as contemplated by the Sixth Circuit, this consideration is of academic interest only. Were the outcome otherwise, it might require further consideration.

order to allege antitrust injury adequately, a plaintiff must allege that the only way the defendant *could* have caused the plaintiff's injury was by engaging in the antitrust violation. Defs. Br. at 32-33. In other words, if the defendant could have in theory caused the same injury without engaging in an antitrust violation, the plaintiff has not suffered an "antitrust injury," even if in fact it was the antitrust violation that caused the actual injury in a particular case. Applied to the present case, the defendants contend that the plaintiffs cannot allege an antitrust injury because Andrx *could* have unilaterally (and legally) decided not to market its generic version of Cardizem CD; they contend it is immaterial whether, in fact, it was the Agreement and the payment of $40 million per year that caused them to do so. *Id.*

We disagree.

First, simply looking at the actual language of the statement suggests that the defendants have conflated two ideas. What the court in *Hodges* said was that in order to survive a motion to dismiss for failure to allege antitrust injury, a plaintiff must allege *either:* (1) that the antitrust violation was "a necessary predicate" to their injury; *or* (2) that the defendants could injure plaintiffs only by engaging in the antitrust violation. 26 F.3d at 39. The defendants' interpretation conflates these options, effectively requiring plaintiffs to satisfy the second one even if they have already satisfied the first.

Second, nothing in the facts or holding of *Axis, Hodges,* or *Valley Products,* the cases relied upon by the defendants, supports their interpretation. Although it does not use the "necessary predicate" language, we consider first the Sixth Circuit's decision in *Axis,* the starting point for this line of

antitrust injury cases.

In *Axis,* 870 F.2d 1105, the plaintiff was a foreign manufacturer of armature winding machines which sought to enter the United States market. After another foreign manufacturer purchased two American manufacturers, the plaintiff filed an antitrust suit against the purchaser claiming that the purchase was illegal because it reduced competition in the armature winding machine market. The plaintiff's alleged injury was its exclusion from the United States market. However, the plaintiff also alleged that it could not enter the market because it lacked access to indisputably valid and essential patents controlled by the defendant; the plaintiff did not challenge the legal right of the patent-holder to refuse to grant it a license. Nor did it or anyone else challenge the validity of the patents. We affirmed dismissal of the complaint because it failed to allege antitrust injury, noting that the "the anticompetitive act of purchasing [the American manufacturer] did not cause the plaintiff's alleged injury. The patents were an *impenetrable* barrier to the plaintiff's entry before [the defendant] purchased [the American manufacturer], and they remained as great a barrier afterwards." 870 F.2d at 1107 (emphasis added).

In *Hodges,* 26 F.3d 39, the plaintiff was an airport shuttle and tour bus operator who wanted to participate in the market for shuttle services from the Nashville airport to Opryland, an amusement park, hotel and convention center. It filed an antitrust suit against the companies that owned the Opryland site and operated the Grand Old Opry music radio program, as well as a sightseeing and tour company known as Grand Old Opry tours. The complaint alleged that those defendants had reached an illegal market division agreement with other shuttle

and tour bus operators that the competitors would refrain from transporting passengers from the airport to the Opryland complex, leaving the airport shuttle market to the defendants themselves. In exchange, the defendants would hire vans and buses from their former competitors for Opryland's sightseeing tour business. The plaintiff's alleged injury was its exclusion from the airport to Opryland shuttle market. The plaintiff further alleged that the defendants policed their illegal agreement by refusing the plaintiff, and any other non-conspiring shuttle service companies, access to the Opryland property; the plaintiff did not challenge the defendants' lawful right to exclude it from their private property. The case was dismissed for failure to allege antitrust injury.

In *Valley Products,* 128 F.3d 398, the plaintiff was a manufacturer of logo- bearing hotel soaps and other hotel amenities which wanted to supply its products to franchisees of a certain hotel franchisor. The hotel franchisor authorized certain vendors to use its trademark on products, which the franchisees would then purchase. After the plaintiff's vendor agreement was terminated, it filed an antitrust suit against the hotel franchisor and its two remaining authorized vendors, the plaintiff's competitors, alleging that their arrangement was an attempt to impose an illegal tying arrangement on franchisees (by conditioning the franchise agreement on the purchase of logoed amenities from the two preferred vendors). There was no allegation that the vendors and the franchisor had agreed to exclude the plaintiff. The plaintiff's alleged injury was its exclusion from the logoed amenity market for the defendant franchisor's franchisees. The case was dismissed for failure to allege antitrust injury. On appeal, we observed that the Sixth Circuit "has been reasonably aggressive in using the antitrust

injury doctrine to bar recovery where the asserted injury, although linked to an alleged violation of the antitrust laws, flows directly from conduct that is not itself an antitrust violation." Valley Products, 128 F.3d at 403.

As the above discussion of *Axis, Hodges* and *Valley Products* demonstrates, the facts and holdings of those cases provide no support for the defendants' proposed interpretation of the "necessary predicate" language in *Hodges.* In none of these cases was a complaint dismissed for failure to allege antitrust injury based on a defendant's claim that it *could* have caused the same injury without committing the alleged violation. Rather, the complaints were dismissed for failure to allege antitrust injury because each of the defendants had taken an action that it was lawfully entitled to take, independent of the alleged antitrust violation, which was the actual, indisputable, and sole cause of the plaintiff's injury. In *Axis,* the antitrust violation was not the "necessary predicate" because the plaintiff's alleged injury--its exclusion from competing in the armature winding machine market--admittedly flowed not from the anticompetitive effects of the allegedly illegal purchase, but from its lack of access to "impenetrable" patents. 870 F.2d at 1107. In *Hodges,* the antitrust violation was not the "necessary predicate" because the plaintiff's alleged injury--its exclusion from competing in the shuttle services from the airport to the Opryland site owned by defendants--actually flowed not from the anticompetitive effects of an allegedly unlawful market division agreement, but from the defendants' "lawful refusal to grant plaintiffs access to their private property." 26 F.3d at 39. In *Valley Products,* the antitrust violation was not the "necessary predicate" because the plaintiff's alleged injury--its exclusion from competing in the franchisor's logoed amenity market--actually flowed, not from the anticompetitive effects of

an allegedly unlawful tying arrangement, but from the defendant's lawful termination of a vendor agreement.[18] Thus, in reality, we have only dismissed a case for failure to allege that an antitrust violation is the "necessary predicate" for the plaintiff's injury where it has been apparent from the face of the complaint that actual and unequivocally legal action by the defendant would have caused plaintiff's injury, even if there had been no antitrust violation.

Application to this case of the "necessary predicate" test, as we have applied it in the cases which are the subject of the certified question, demonstrates that the district court correctly refused to dismiss these complaints for failure to allege antitrust injury. In essence, as exposed by the *per se* analysis above, *see supra* Part II.A., the complaints allege a plain vanilla horizontal agreement to restrain trade in the form of a multi-million dollar cash payment in consideration for forbearance by Andrx from selling on the market a product that it was ready and able to sell at a price lower than that charged by HMR for the patented product. There is nothing on the face of the complaint that suggests, much less establishes as a matter of law, that there was any physical or "impenetrable" legal impediment to Andrx's production and sale of its FDA-approved generic product. Indeed, some plaintiffs allege that HMR's patent infringement suit against Andrx was a "sham." JA 948, ¶ 101; JA 949, ¶¶ 103-04; JA 154, ¶ 53. Nor can the defendants identify a lawful right that they had and exercised and that

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[18] This court's decision in *Watkins & Son Pet Supplies v. Iams Co.*, 254 F.3d 607 (6th Cir.2001), similarly found no antitrust injury where the plaintiff's alleged injury--its exclusion from the market--flowed from the termination of its distributorship, not from the defendants' allegedly illegal distribution restraints.

indisputably caused plaintiffs' injury. Thus, the complaint may be fairly construed as alleging that the *per se* illegal Agreement with its $89 million payment, not HMR's disputed 45%-18 patent, constituted the "necessary predicate" for Andrx's decision to keep its FDA-approved 55%-18 generic product off the market and HMR free from *any* generic product competition. The fact that Andrx could have unilaterally, and legally, decided not to bring its generic product to a manifestly profitable market has no relevance in assessing whether the plaintiffs adequately alleged that the antitrust violation was the necessary predicate for their injury. [19]

What remains is the defendants' contention that Andrx would have stayed out of the market even absent the Agreement and the payment of $40 million per year because Andrx feared incurring damages in the patent infringement litigation. Proof of allegations on the face of this complaint and reasonable inferences therefrom, however, could persuade a trier of fact that had HMR been confident of the independent durability of its patent and the validity of its infringement claim, it would not have paid $89 million to effect what the patent and infringement suit had already accomplished. Under the aegis of the complaint and inferences, a fact trier could also find that even if it is a "prudent" industry practice for a generic manufacturer to stay out of the market until the resolution of patent infringement litigation, Defs. Br. at 33, in this case, the

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[19] In addition, the defendants' position, if adopted, risks undermining a basic premise of antitrust law that, as the district court observed, in many instances, an otherwise legal action--*e.g.* setting a price--becomes illegal if it is pursuant to an agreement with a competitor. Under the defendants' view, such an action would never cause antitrust injury because a defendant *could* have unilaterally and legally set the same price.

patent infringement suit was a "paper tiger" incapable of deterring the generic producer from entering the market as soon as the FDA approved its product--as it had formally advised the patent court. If proved to be true, it would almost necessarily follow that the plaintiffs' injury flowed from the Agreement and payment of $40 million per year. At this stage of the litigation, we must leave this dispute for the trier of fact to evaluate.

## III. CONCLUSION

For the foregoing reasons, we answer both of the district court's certified questions as follows: it properly resolved the questions that it put to us in the course of denying defendants' motions to dismiss and granting the plaintiffs' motions for summary judgment that the defendants had committed a per se violation of the antitrust laws.

**AGREEMENT**

This Agreement ("Agreement") is made and entered into this 1st day of April, 1998, between Geneva Pharmaceuticals, Inc. and Abbott Laboratories.

WHEREAS, Geneva Pharmaceuticals, Inc. ("Geneva") has submitted an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Abbott Laboratories' ("Abbott's") HYTRIN® (terazosin hydrochloride) tablets, which has been designated as ANDA No. 74-315, and has submitted an ANDA to the FDA seeking approval to market a generic version of Abbott's HYTRIN® (terazosin hydrochloride) capsules, which has been designated as ANDA No. 74-823;

WHEREAS, Abbott is the owner of United States Patent No. 5,504,207 ("the '207 patent")m which claims, *inter alia*, Form IV anhydrous terazosin hydrochloride;

WHEREAS, Geneva has acknowledged that its proposed generic terazosin hydrochloride tablets and proposed generic terazosin hydrochloride capsules would infringe claim 4 of Abbott's '207 patent, if valid and enforceable;

WHEREAS, Abbott and Geneva acknowledge that an actual controversy exists between them concerning the validity and enforceability of the '207 patent, which is the subject of *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, Case No. 96 C 3331, pending in the United States District Court for the Northern District of Illinois;

WHEREAS, Geneva has recently obtained final FDA approval of its ANDA No. 74-823 for a generic terazosin hydrochloride capsule product; and

WHEREAS, the Parties desire to avoid the risk and expenses associated with emergency litigation with respect to the validity and enforceability of the '207 patent and its impact on Geneva's rights to market its proposed generic terazosin hydrochloride capsules;

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement, Abbott and Geneva agree as follows:

**Definitions**

1. "Abbott" means Abbott Laboratories, as well as its Affiliates, successors in interest, and assigns.

2. "Geneva" means Geneva Pharmaceuticals, Inc. as well as its Affiliates, successors in interest, an assigns.

3. "Affiliate" of any Party means any entity which, directly or indirectly, owns or controls, is under common ownership or control with, or is owned or controlled by such Party.

4. "Party" or "Parties" means Geneva and/or Abbott as defined in Paragraphs 1 and 2 of this Agreement.

5. "Case No. 96 C 3331" means *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, now pending in the United States District Court for the Northern District of Illinois, and

any appeal taken therefrom.

6. "FDA" means the United States Food and Drug Administration.

7. "Terazosin Hydrochloride Product" means any pharmaceutical product, regardless of formulation or dosage form (tablet, capsule, etc.), containing terazosin hydrochloride.

8. "The '207 patent" means Abbott's United States Patent No. 5,504,207.

9. "ANDA" means an abbreviated new drug application submitted to the FDA pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act. 21 U.S.C. § 355(j).

10. "Commercial Sale" means the introduction or delivery for introduction into commerce of a drug product approved by the FDA, but does not include transfer of the drug product for reasons other than sale or for investigational use under 21 C.F.R. Part 312.

11. "Generic Entry" means the first Commercial Sale in the United States by any person other than Geneva of a Terazosin Hydrochloride Product that was manufactured pursuant to an ANDA approved by the FDA.

12. "Generic Entry Date" means the earlier of (a) the first date on which either Party provides notice in good faith (including all facts or evidence of such Generic Entry known to the Party sending such notice), pursuant to Paragraph 32 of this Agreement, to the other Party of the occurrence of Generic Entry; or (b) the last of (i) the expiration date for Abbott's

United States Patent No. 4,251,532 or (ii) the expiration of any statutory exclusivity period provided to Abbott by law for Terazosin Hydrochloride Products.

13. "Final Judgment in Abbott's Favor" means the entry pursuant to Federal Rule of Civil Procedure 79(a) by the United States District Court for the Northern District of Illinois in Case No. 96 C 3331 of a final, appealable judgment the Geneva's Terazosin Hydrochloride Products infringe or would infringe any valid and enforceable claim of the '207 patent.

14. "Final Judgment in Geneva's Favor" means the entry pursuant to Federal Rule of Civil Procedure 79(a) by the United States District Court for the Northern District of Illinois in Case No. 96 C 3331 of a final, appealable judgment that Geneva's Terazosin Hydrochloride Products do not infringe or would not infringe any valid and enforceable claim of the'207 patent.

15. "Appellate Judgment" means (a) if neither Party timely files a notice of appeal from a Final Judgment, the first date after which the time for filing a notice of appeal under the Federal Rules of Appellate Procedure has expired; (b) if neither Party timely files a Petition for Writ of Certiorari, the date that a mandate issues from the United States Court of Appeals for the Federal Circuit on an appeal from a Final Judgment in Geneva's Favor or a Final Judgment in Abbott's favor, or (c) if either Party timely files a Petition for Writ of Certiorari in the United States Supreme Court, the date of the opinion or order of the Supreme Court disposing of the case; provided, however, that as to both clauses (b) and (c) of this Paragraph, a remand to the District Court or to the United States Court of Appeals for the Federal Circuit for further substantive proceedings shall not constitute an Appellate Judgment.

**Payments**

16. On April 30, 1998, and thereafter on the fifth business day after the end of each calendar month beginning with May, 1998, Abbott shall pay to Geneva $4,500,000 by wire transfer pursuant to wire instructions provided by Geneva. Provided, however, that:

(a) Abbott shall not be obligated under any circumstances to pay any sums for any period of time after the Generic Entry Date and, as the month in which the Generic Entry Date occurs, Abbott shall pay Geneva a prorated portion of the $4,500,000 for the time period in such month prior to the Generic Entry Date.

(b) Abbott shall not be obligated under any circumstances to pay any sums for any period of time after the date of a Final Judgment in Abbott's Favor, and as to the month in which the Final Judgment in Abbott's Favor occurs, Abbott shall pay Geneva a prorated portion of the $4,500,000 for the time period in such month prior to the date of the Final Judgment in Abbott's Favor.

(c) If a Final Judgment in Geneva's Favor is entered, Abbott shall pay to Geneva a prorated portion of the $4,500,000 for the time period in such month prior to the date of the Final Judgment in Geneva's Favor.
Thereafter, as to the remainder of the month in which the Final Judgment in Geneva's Favor is entered, Abbott shall pay into escrow a prorated

portion of $4,500,000 for the time period in such month after the date of the Final Judgment in Geneva's Favor. The escrowed payment shall be held with an escrow agent, and pursuant to escrow arrangements, reasonably acceptable to both Parties. Escrowed payments at the rate of $4,500,000 per month shall continue until the earlier of the Generic Entry Date, the Appellate Judgment, or the date of a Final Judgment in Abbott's Favor.

(i) If the Appellate Judgment provides that Geneva's Terazosin's Hydrochloride Products do not infringe or would not infringe any valid and enforceable claim of the '207 patent, Abbott shall take all steps necessary to release to Geneva any such escrowed amount, with interest, if any, no later than the fifth business day after the Appellate Judgment;

(ii) If the Appellate Judgment provides that Geneva's Terazosin Hydrochloride Products infringe or would infringe any valid and enforceable claim of the '207 patent, Geneva shall take all steps necessary to release to Abbott any such escrowed

amount, with interest, if any, no later than the fifth business day after the Appellate Judgment; or

(iii) If, after monies have been paid into escrow pursuant to Paragraph 16(c), there is a Final Judgment in Abbott's Favor, then Geneva shall take all steps necessary to release to Abbott any such escrowed amount, with interest, if any, no later than the fifth business day after the Final Judgment in Abbott's Favor.

(d) If the Generic Entry Date has not occurred on or before February 18, 2000, Abbott shall have the option of terminating its payment obligations under this Paragraph 16 upon thirty (30) days' written notice to Geneva. If Abbott elects to terminate its payment obligations, Abbott shall provide Geneva with a covenant not to sue it for patent infringement on Geneva's Terazosin Hydrochloride Product(s) under claim 4 of the '207 patent.

**Other Covenants**

17. Geneva affirms that (i) as of the date of this Agreement it is the owner of ANDA No. 74-315 for terazosin hydrochloride tablets, and ANDA No. 74-823 for terazosin hydrochloride capsules; (ii) that ANDA No. 74-823 and ANDA No. 74-315 are the only ANDAs Geneva has submitted for

approval of any Terazosin Hydrochloride Product; (iii) that Geneva has not assigned or transferred, and shall not assign or transfer, its rights under either ANDA No. 74-315 or under ANDA No. 74-823 to any other entity; and (iv) that Geneva has obtained final marketing approval from the FDA for ANDA No. 74-823.

18. The Parties agree that a Final Judgment in Abbott's Favor, a Final Judgment in Geneva's Favor and/or an Appellate Judgment in Case No. 96 C 3331 apply with equal force and binding effect as to Geneva's rights under ANDA No. 74-823. The Parties agree to take any steps necessary to effectuate this Paragraph; provided, however, that Geneva is not agreeing hereby to consent to the amendment of the Complaint in Case No. 96 C 3331 to include a claim by Abbott that Geneva's terazosin hydrochloride capsules infringe the '207 patent.

19. Geneva agrees to join and support any motion filed by Abbott in Case No. 96 C 3331, Case No. 96 C 5868 and/or Case No. 97 C 7587, pending in the United States District Court for the Northern District of Illinois, which seeks an extension of any 30-month period provided by 21 U.S.C. § 355(j)(4)(B)(iii) up to and including the Appellate Judgment.

20. Except as permitted in Paragraph 16(d), Geneva shall not sell, offer for sale, donate, or otherwise distribute in the United States any Terazosin Hydrochloride Product until after the earlier of (1) the Generic Entry Date, or (2) the Appellate Judgment.

21. Geneva agrees to use its best efforts to oppose any attempts by any ANDA applicant that is a party to litigation involving terazosin hydrochloride patents to assert that it is

entitled to approval of its ANDA for a Terazosin Hydrochloride Product prior to the date currently determined pursuant to 21 C.F.R. § 314.107.

**Confidentiality**

22. The financial terms of this Agreement, including, but not limited to the terms of Paragraph 16 of this Agreement, shall remain confidential to the Parties, and shall not be disclosed to third parties; provided, however, that the disclosure of the financial terms of this Agreement shall not be considered a breach of this Agreement where ordered by a court in a legal proceeding, or otherwise required by law in the opinion of the Party's legal counsel. In such event, however, the Party disclosing the financial terms of this Agreement must (a) notify the other Party of the nature, content, and source of any request or demand for disclosure of such terms immediately upon receipt of such request or demand; (b) oppose a request or demand for a disclosure of such information; (c) give 3 business days' prior written notice to the Party of the nature and content of the disclosure and of the person(s) to whom such disclosure shall be made; and (d) reasonably consider any comments made by the other Party concerning the nature, content and extent of such disclosure.

**Remedies and Dispute Resolution**

23. Except as provided in Paragraph 24, the Parties agree that any dispute arising under this Agreement must be resolved in accordance with the Alternative Dispute Resolution ("ADR") procedures attached as Exhibit A. The Parties consent to the jurisdiction of the United States District Court for the Northern District of Illinois and agree that such court is the sole

proper forum for any actions in enforcement of this Agreement.

24. In addition to any other rights or remedies Abbott may have for breach of this Agreement, Abbott specifically reserves the right to seek temporary, preliminary and permanent injunctive relief in the United States District Court for the Northern District of Illinois if Geneva breaches Paragraph 20 of this Agreement.

**Other Provisions**

25. The Parties understand that, subject to the provisions of this Agreement, Geneva intends to use its best efforts to obtain any statutory period exclusive marketing to which it may be entitled under 21 U.S.C. § 355(j)(4)(B)(iv).

26. Each Party agrees that, at the request of the other, it will cooperate fully in seeking a stay of mandate pursuant to Federal Rule of Appellate Procedure 41(b) pending a Petition for Writ of Certiorari to the Supreme Court.

27. The Parties agree that this Agreement has been negotiated at arms' length and between persons sophisticated and knowledgeable in the matters dealt with here. Each party has been represented by experienced and knowledgeable counsel. Accordingly, any rule of law or legal decision that would interpret ambiguities against the drafter is not applicable and is waived. The provisions of this Agreement shall be interpreted in a reasonable manner to effect the purpose of the Parties and this Agreement.

28. This Agreement and any exhibits attached hereto constitute the entire agreement between the Parties and

supersede any prior understandings, agreements or representations by and between the Parties regarding this Agreement, written or oral.

29. This Agreement may be amended only by a writing executed by each of the Parties.

To Geneva: President
Geneva Pharmaceuticals, Inc.
2655 W Midway Boulevard
Broomfield, Colorado 80038
Telecopy: 303/466-6378

Notice is effective upon a receipt by the sender of a confirmation from the sender's telecopier of sending the telecopy to the attention of the above-identified individuals.

This Agreement has been duly executed and delivered by an authorized representative of each of the following Parties and will be valid and binding against each of them.

**DATE:** April 7, 1998

**GENEVA PHARMACEUTICALS, INC.**

AGREED TO AND ACCEPTED

By: S/
Title: Senior Vice President
Bus. Div. And General Counsel

**DATE:** April 1, 1998

**ABBOTT LABORATORIES**

AGREED TO AND ACCEPTED

By: S/

Title: President, Pharmaceutical Products Division

## SETTLEMENT AGREEMENT

The Settlement Agreement ("Agreement") is made and entered into this 31 day of March, 1998 by and among Zenith Laboratories, Inc., Zenith Goldline Pharmaceuticals, Inc., IVAX Corporation and Abbott Laboratories.

WHEREAS, Zenith Laboratories, Inc. and Abbott Laboratories are parties to *Zenith Laboratories, Inc. v. Abbott Laboratories,* Civil Action No. 96 Civ. 1661, pending in the United States District Court for the District of New Jersey ("the Civil Action") and Appeal No. 98-1026, pending in the United States Court of Appeals for the Federal Circuit ("the Appeal");

WHEREAS, Zenith and Abbott desire to avoid the risks and expenses associated with litigation and to settle the Civil Action and the Appeal amicably as set forth in this Agreement, without either Party admitting any liability to the other Party;

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement, Zenith and Abbott agree as follows:

**Definitions**

1. "Zenith" means Zenith Laboratories, Inc., a Florida corporation, Zenith Goldline Pharmaceuticals, Inc., and IVAX Corporation and all of their respective subsidiaries, affiliates, successors in interest, and assigns.

2. "Abbott" means Abbott Laboratories, and Illinois corporation, as well as its subsidiaries, affiliates, successors in

interest, and assigns.

3. "Party" or "Parties" means Zenith and/or Abbott as defined in Paragraphs 1 and 2 of this Agreement.

4. "FDA" means the United States Food and Drug Administration.

5. "ANDA" means an abbreviated new drug application submitted to the FDA pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(J).

6. "Commercial Sale" means the introduction or delivery for introduction into commerce of a drug product approved by the FDA, but does not include transfer of the drug product for reasons other than sale or for investigational use under 21 C.F.R. Part 312.

7. "Generic Terazosin Hydrochloride Product" means FDA approved Terazosin Hydrochloride Product, excluding Abbott's branded Terazosin Hydrochloride Products sold and/or marketed under the HYTRIN® trademark.

7(a) "Generic Entry" means the first Commercial Sale in the United States by any person or entity including Abbott, but excluding Zenith, of a Generic Terazosin Hydrochloride Product.

8. "Generic Entry Date" means the earlier of 1) the date of Generic Entry; or 2) the last of (a) the expiration date for Abbott's U.S. Patent No. 4,251,532 (the "532 Patent") (which currently is due to expire on February 17, 2000); or (b) the expiration of any statutory exclusivity period provided to

Abbott by law for Terazosin Hydrochloride Products.

9. "Generic Exclusivity Period" means the period of time, not to exceed one hundred eighty (180) days, during which Zenith can sell no Terazosin Hydrochloride Product because the FDA has not granted to Zenith final marketing approval solely because of the provisions of 21 U.S.C. §355(j)(4)(B)(iv).

10. "Terazosin Hydrochloride Product" means any pharmaceutical product, regardless of formulation or dosage form (tablet, capsule, etc.), containing terazosin hydrochloride.

11. "Abbott's Terazosin Hydrochloride Patents" means (1) U.S. Patent Nos. 4,251,532, 5,212,176, 5,268,182, 5,294,615, 5,362,730, 5,412,095, and/or 5,504,207, and any later reissues or reexaminations of any such patents; (2) any patent issued to Abbott by the United States Patent and Trademark Office from a patent application pending as of the date of execution of this Agreement, which specifically claims any process for making terazosin hydrochloride, or any form, any use, or any formulation, of terazosin hydrochloride; or 3) any other U.S. patent currently or hereafter owned by, assigned to, licensed by, or asserted by Abbott that would be infringed by the manufacture, use, sale or importation of any Terazosin Hydrochloride Product currently the subject of commercial sales or the subject of Zenith's current ANDA #74-530.

12. "Payment Period" means one of the payment periods described in Paragraph 16(a) of this Agreement.

13. "Orange Book" means the FDA publication entitled *Approved Drug Products With Therapeutic Equivalence Evaluations.*

**Dismissal of Action**

14. Concurrently with the execution of this Agreement, the Parties shall execute and immediately file a Stipulation of Dismissal With Prejudice, in the form attached as Exhibit A to this Agreement, which dismisses the Civil Action with prejudice and provides that each party bear its own costs and attorneys' fees. The Parties shall take all other appropriate and reasonable actions necessary to ensure that this Stipulation is effectuated as soon as possible.

15. Concurrently with the execution of this Agreement, the Parties shall execute and immediately file a Stipulation of Dismissal of Appeal, in the form attached as Exhibit B to this Agreement, which dismiss the Appeal with prejudice as moot, and provides that each party shall bear its own costs and attorneys' fees. The Parties shall take all other appropriate and reasonable actions necessary to ensure that the Stipulation is effectuated as soon as possible and that any orders or opinions on the merits issued by the United States Court of Appeals for the Federal Circuit after March 23, 1998 be vacated and withdrawn as moot; provided, however, that the failure or refusal of the Court of Appeals to vacate or withdraw any such order or opinion shall not excuse the Parties' performance under this Agreement.

**Payments**

16. Abbott shall pay Zenith the sum of $3,000,000 within one (1) business day after the filing of the Stipulations of Dismissal in the Civil Action and the Appeal. Such payment shall be non-refundable and shall not be subject to reduction or

proration; provided, however, that if for any reason the District Court falls or refuses to dismiss the Civil Action with prejudice, then this Agreement shall terminate and become null and void, and any monies paid by Abbott to Zenith hereunder shall be immediately returned, and the Parties shall be deemed to have reverted to their respective status prior to the execution of this Agreement and shall proceed in all respects as if this Agreement had not been entered into, preserving in that event all of their respective claims and defenses in the Civil Action and the Appeal. Thereafter, assuming that the District Court has dismissed the Civil Action with prejudice, Abbott's payment obligations to Zenith shall be as follows:

(a) Abbott shall make payments to Zenith on the Payment Date as set forth in Table 1 for each full Payment Period that ends prior to the Generic Entry Date:

**TABLE 1**

| Payment Period | Payment Date | Payment Amount (U.S. Dollars) |
|---|---|---|
| 4/1/98 - 6/30/98 | 7/15/98 | $3,000,000.00 |
| 6/31/98 - 9/30/98 | 10/15/98 | $6,000,000.00 |
| 10/1/98-12/31/98 | 1/15/99 | $6,000,000.00 |
| 1/1/99 - 3/31/99 | 4/15/99 | $6,000,000.00 |
| 4/1/99 - 6/30/99 | 7/15/99 | $6,000,000.00 |
| 7/1/99 - 9/30/99 | 10/15/99 | $6,000,000.00 |

| | | |
|---|---|---|
| 10/1/99-12/31/99 | 1/15/00 | $6,000,000.00 |
| 1/1/00 - 2/17/00 | 3/1/00 | $3,164,835.00 |

Abbott shall not be obligated to make the payments specified in Table 1 for the Payment Period in which the Generic Entry Date occurs or for any subsequent Payment Periods. Instead, Abbott shall be obligated only to make those payments required by Paragraphs 16(b) and (c) of this Agreement.

If the Generic Entry Date has not occurred on or before February 18, 2000, then Abbott shall not make the payment corresponding to the March 1, 2000 Payment Date above, and shall instead (if the Generic Entry Date has not occurred by March 31, 2000) make payment to Zenith of $6 million on April 15, 2000. If the Generic Entry Date occurs after February 18, 2000 but before April 1, 2000, then the payment required shall be calculated in accordance with Paragraph 16(b). For purposes of this Agreement, April 15, 2000 shall be deemed a Payment Date, and the $6 million shall be deemed a Payment Amount. The Payment Period shall be from 1/1/00 to 3/31/00.

(b) With respect to the Payment Period, if any, in which the Generic Entry Date occurs, Abbott shall pay Zenith, on the Payment Date for such Payment Period, a prorated amount for that portion of the Payment Period that ended prior

to the Generic Entry Date. Such prorated payment shall be calculated in accordance with the following formula:

(number of days in Payment Period to the Generic Entry Date) X (Payment Amount for such Payment Period)

(total number of days in such Payment Period)

(c) If no Generic Exclusivity Period occurs, Abbott shall have not further payment obligation to Zenith after the Generic Entry Date. If a Generic Exclusivity Period occurs, the Abbott shall pay to Zenith, on the Payment Date(s) specified in Paragraph 16(a), a prorated amount for the duration of the Generic Exclusivity Period, calculated in accordance with the following formula:

(number of days in Payment Period on and after the Generic Entry Date but during the Generic Exclusivity Period) X (½ of the Payment Amount for such Payment Period)

(total number of days in such Payment Period)

(d) Abbott shall have no obligation to pay Zenith any sums relating to any Payment Period after

the expiration of the Generic Exclusivity Period, regardless of whether the FDA further delays or withholds the approval of Zenith's ANDA(s) for the Terazosin Hydrochloride Product.

(e) If the Generic Entry Date has not occurred on or before March 31, 2000 (thereby obligating Abbott to pay Zenith $6 million on April 15, 2000 pursuant to Paragraph 16(a)). Abbott shall have the option (on a calendar quarter by calendar quarter basis) of (i) continuing to pay Zenith the amount of $6 million per calendar quarter thereafter until the Generic Entry Date occurs, or (ii) allowing Zenith to enter the market as if Generic Entry Date had occurred. Abbott shall be deemed to have elected option (i) unless Abbott gives Zenith notice thirty (30) days prior to the start of the calendar quarter that Abbott shall make the required payment to Zenith and Zenith shall refrain from selling a Terazosin Hydrochloride Product until the Generic Entry Date occurs. Any such payment shall be made on the 15th day of the month following the end of each calendar quarter. If the Generic Entry Date occurs during the middle of any such calendar quarter, the payment shall be prorated in accordance with the following formula:

(number of days in calendar quarter prior to the Generic Entry Date) X ($6 Million)
(total number of days in such

calendar quarter)

**Covenants**

17. Except as permitted in Paragraph 16(e)m Zenith shall not sell, offer for sale, donate, or otherwise commercially distribute in the United States any Terazosin Hydrochloride Product until the Generic Entry Date.

18. In the event that the Generic Entry Date occurs prior to the expiration date of the '532 Patent, and thereafter all generic competitors, other than Zenith, who have commenced commercial sale of Terazosin Hydrochloride Products cease selling all such products in the United States due to legal action brought by Abbott enforcing any Abbott Terazosin Hydrochloride Patent, such that there is no generic competition to Abbott's branded Terazosin Hydrochloride Products other than Zenith, the following shall apply:

(i) Abbott shall notify Zenith of the occurrence of the foregoing events, including the commencement of any legal action described above and shall keep Zenith reasonably apprised of the progress of such proceedings, and Abbott shall cease selling, on or before the date following 3 business days of the sending of notice to Zenith of the withdrawal from the market of all generic competitors, any generic Terazosin Hydrochloride Product that it has launched:

(ii) On the date following 3 business days after receipt of notice from Abbott of the withdrawal from the market of all generic competitors, Zenith shall not sell, offer for sale, donate or otherwise commercially distribute in the United

States any Terazosin Hydrochloride Product until the reoccurrence of a Generic Entry Date.

(iii) Abbott shall reinstitute the payments required by Paragraph 16 of this Agreement, which shall be prorated to cover only the period during which Zenith does not sell any Terazosin Hydrochloride Product; and

(iv) upon the reoccurrence of a Generic Entry Date, the Parties shall treat such further Generic Entry Date as triggering all of the respective rights and obligations under this Agreement which were triggered as of the original Generic Entry Date.

19. Zenith and Abbott mutually covenant to provide notice to the order in the manner provided in Paragraph 35 of their respective first Commercial Sale[s] of any Generic Terazosin Hydrochloride Product. Such notice shall be given no later than the end of the business day on the sale date of such first Commercial Sale.

20. Excluding any action for breach of this Agreement, Zenith covenants to refrain from taking any action or assisting any other person or entity in taking action, against Abbott with respect to Abbott's Terazosin Hydrochloride Patents including but not limited to (a) any interference or other proceeding before the United States Patent & Trademark Office: (b) any cause of action relating to non-infringement, invalidity, or unenforceability of any of Abbott's Terazosin Hydrochloride Patents, or regarding the propriety of their listing in the Orange Book; (c) any cause of action based upon an act or omission of Abbott up until date of this Agreement relating to Zenith's entry into the market with a Terazosin Hydrochloride Product;

and (d) any other action, including but not limited to tort actions, relating to Abbot's use, assertion or enforcement of its Terazosin Hydrochloride Patents.

21. Excluding any action for breach of this Agreement, Abbott covenants to refrain from taking any action, or assisting any other person or entity in taking any action, before or against the FDA or any other legal or regulatory body with respect to any Zenith ANDA that seeks to market a formulation of a Terazosin Hydrochloride Product currently approved under Abbott NDA ("Zenith ANDA") which intends to delay or prevent, or which delays or prevents, the approval of any Zenith ANDA. Also excluding any action for breach of this Agreement, Abbott further covenants that as of the date that Zenith is permitted under the terms of this Agreement to manufacture, have manufactured, market, use, import or sell Terazosin Hydrochloride Products (a) Abbott will refrain from claiming, orally or in writing, or through legal action or proceeding, that Zenith's manufacture, marketing, use, or sale of a Terazosin Hydrochloride Product which is the subject of any Zenith ANDA, or the importation of terazosin hydrochloride for use in the manufacture of a Terazosin Hydrochloride Product under any Zenith ANDA, infringes Abbott's Terazosin Hydrochloride Patents; (b) Abbott will refrain from asserting a claim for patent infringement or contributory patent infringement of Abbott's Terazosin Hydrochloride Patents against Zenith's customers arising from such customers' purchase or resale of Zenith's Terazosin Hydrochloride Product; and (c) to the extent that Abbott obtains a judgment of patent infringement against any supplier of terazosin hydrochloride, Abbott will refrain from enforcing such judgment with respect to that supplier's use, manufacture and sale of terazosin hydrochloride for use in Zenith's

manufacture of a Terazosin Hydrochloride Product.

22. Simultaneously with the execution of this Agreement, the Parties shall execute the Covenant Not To Sue attached hereto as Exhibit C. In the event that Abbott's obligations under Paragraph 21 of this Agreement are relieved for any reason, Abbott's obligations under this Covenant Not To Sue are similarly relieved.

23. Zenith recognizes and acknowledges the validity and enforceability of each of Abbott's Terazosin Hydrochloride Patents, and of each and every claim contained therein, Zenith further acknowledges that any potential Terazosin Hydrochloride Product it would market would infringe at least one of Abbott's Terazosin Hydrochloride Patents. Abbott agrees not to introduce into evidence Zenith's recognition and acknowledgment of the validity and enforceability and infringement of Abbott's Terazosin Hydgrochloride Patents set forth in this Paragraph in defense against a claim of invalidity or unenforceability of any of Abbott's Terazosin Hydrochloride Patents and shall not otherwise introduce into evidence, assert or use offensively or defensively in any way this recognition and acknowledgment against any of Zenith's raw material suppliers, including specifically Byron Chemical Company or Uetikon, provided, however, that Abbott may assert this recognition and acknowledgment as a defense to a claim arising in any way out of or as a result of this Agreement. Furthermore, this recognition and acknowledgment shall not be binding on any of Zenith's raw material suppliers, including Byron Chemical Company or Uetikon.

24. Zenith confirms that as of the date of this Agreement it is the owner of ANDA No. 74-530, for a Terazosin

Hydrochloride Product, and that it is has not assigned or transferred, and shall not assign or transfer, its rights under ANDA No. 74-530, or any other ANDA related to a Terazosin Hydrochloride Product, to any other entity other than one of its corporate affiliates, provided that Zenith shall guarantee such affiliate's performance of this Agreement. Additionally, and notwithstanding anything in this Agreement to the contrary, Zenith may assign ANDA No. 74-530 (and its rights thereunder), together with its rights and obligations under this Agreement, in connection with any sale of all or substantially all of its business. Zenith agrees that it shall promptly furnish to Abbott a copy of any letter to Zenith from the FDA, granting approval (including tentative approval) of any ANDA for a Terazosin Hydrochloride Product.

25. Zenith agrees that is shall not aid or assist any other person or entity to gain FDA approval to market a Terazosin Hydrochloride Product; provided, however, that nothing in this paragraph or Agreement shall prohibit Zenith from complying with any lawfully issued subpoena or other discovery request. In the event that Zenith is served with a subpoena or discovery request which calls for the production or disclosure of materials or information which have been produced by Abbott to Zenith in the Civil Action and which have been designated "Confidential" or "Confidential-Attorney's Eyes Only" by Abbott pursuant to the Protective Order entered in the Civil Action, then Zenith will provide Abbott notice of such subpoena or discovery request prior to complying therewith.

26. Abbott affirms that U.S. Patent Nos. 4,251,532, 5,212,176, 5,268,182, 5,294,615, 5,362,730, 5,412,095, and 5,504,207 are all the United States patents issued to or owned by Abbott that specifically claim any process for making, any

form, any use, or any formulation, of terazosin hydrochloride.

**Releases**

27. Except for the rights and obligations set forth in this Agreement, Zenith releases and forever discharges Abbott and its shareholders, directors, officers, employees, and attorneys, from any and all claims, demands, damages, actions, causes of action or liability of any kind or nature whatsoever, known or unknown, asserted or unasserted, existing or contingent, direct or derivative, that may now exist or which may hereafter be acquired, relating to any acts or omissions by Abbott in the United States up until the date of execution of this Agreement, which relate in any way to terazosin hydrochloride, including but not limited to any claim that Abbott improperly submitted any of its Terazosin Hydrochloride Patents for listing in FDA's Orange Book, that Abbott acted improperly in obtaining or enforcing any of its Terazosin Hydrochloride Patents, or any claims or causes of action that were or could have been raised in the Civil Action or the Appeal.

28. Except for the rights and obligations set forth in this Agreement, Abbott releases and forever discharges Zenith and its shareholders, directors, officers, employees and attorneys, from any and all claims, demands, damages, actions, causes of action or liability of any kind or nature whatsoever, known or unknown, asserted or unasserted, existing or contingent, direct or derivative, that may now exist or which may hereafter be acquired, relating to any acts or omissions by Zenith in the United States up until the date of execution of this Agreement, which relate in any way to terazosin hydrochloride, including

but not limited to any claims or causes of action that were or could have been raised in the Civil Action or the Appeal.

**Press Release**

29. The Parties agree that if either of them intends to issue a written press release concerning or describing this Agreement, then with respect to any such press release, the party intending to issue such release shall provide the other party with an advance text of such release at least one (1) full business day prior to its issuance. The text of the press release shall be provided in the manner provided in Paragraph 35. This advance text shall be provided for information purposes only, and the party receiving such advance text shall have no right, authority or power to change or revise the content or the wording of the release. The party providing advance notice of such release shall be permitted to redact all portions of such release which do not relate to this Agreement. The party receiving an advance copy of any such release agrees to maintain the draft release is issued publicly. This paragraph shall not apply to any public statements other than in the form of a press release.

**Other Provisions**

30. No Construction Against Drafter. The Parties agree that this Agreement has been negotiated at arms length and between persons sophisticated and knowledgeable in the matters dealt with here. Each party has been represented by experienced and knowledgeable counsel. Accordingly, any rule of law or legal decision that would interpret ambiguities against the drafter is not applicable and is waived. The provisions of this Agreement

shall be interpreted in a reasonable manner to effect the purpose of the Parties and this Agreement.

31. Entire Agreement. This Agreement and the exhibits attached hereto constitutes the entire agreement between the Parties regarding settlement of the Civil Action and the Appeal and supersedes any prior understandings, agreements or representations by and between the Parties regarding this settlement, written or oral.

32. Amendments. This Agreement may be amended only by a writing executed by each of the Parties.

33. Miscellaneous. This Agreement shall be binding upon and shall inure to the benefit of the Parties' respective successors and assigns. All payments under this Agreement shall be made by wire transfer to an account designated by Zenith.

34. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same instrument.

35. Notice. The Parties agree that any notice to be given pursuant to this Agreement shall be made by telecopy and, on that same day, by overnight courier service upon the following individuals:

| | |
|---|---|
| To Abbott: | President<br>Pharmaceutical Products<br>Division<br>Dep't 309, Bldg. AP30<br>Abbott Laboratories<br>200 Abbott Park Road<br>Abbott Park, Illinois 60064-3537<br>Telecopy: (847) 938-5383 |
| with a copy to: | General Counsel<br>Legal Division<br>Dep't 364, Bldg. AP6D<br>Abbott Laboratories<br>100 Abbott Park Road<br>Abbott Park, Illinois 60064-3500<br>Telecopy: (847) 938-6277 |
| To Zenith: | President<br>Zenith Goldline<br>Pharmaceutical, Inc.<br>4400 Biscayne Boulevard<br>Miami, Florida 33137-3212<br>Telecopy: (305) 575-4105 |
| with copy to: | General Counsel<br>IVAX Corporation<br>4400 Biscayne Boulevard<br>Miami Florida 33137-3212<br>Telecopy: (305) 575-4105 |

Notice is effective upon receipt by the sender of a confirmation from the sender's telecopier of a sending of the telecopy to the attention of the above-identified individuals.

36. A prevailing party shall be entitled to any reasonable attorney's fees and court costs incurred in enforcing this Agreement or in defending any action brought in violation hereof.

This Agreement has been duly executed and delivered by an authorized representative of each of the following Parties and will be valid and binding against each of them.

**DATE:** March 31, 1998

ZENITH
LABORATORIES, INC.

AGREED TO AND ACCEPTED

By: S/
Rafick G. Henein
Title: President

**DATE:** March 31, 1998

ZENITH GOLDLINE
PHARMACEUTICALS, INC.

AGREED TO AND ACCEPTED

By: S/
Rafick G. Henein
Title: President and Chief
Executive Officer

**DATE:** Mar 31, 1998

IVAX CORPORATION

AGREED TO AND ACCEPTED

By: S/
David R. Bethune
Title: President and Chief
Operating Officer

**DATE:** March 31, 1998

ABBOTT LABORATORIES

AGREED TO AND ACCEPTED

By: S/
Title: President
Pharmaceutical Products
Division